CENTER FOR MILITARY HEALTH POLICY RESEARCH

Army Medical Support to the Army After Next

Issues and Insights from the Medical Technology Workshop, 1999

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PREFACE

This report describes the Army Medical Department's participation in the Medical Technology Workshop-99, one of the Army After Next franchise games sponsored by the U.S. Army Training and Doctrine Command. These exercises are designed to link Army XXI to a long-term vision of the Army, extending well into the twenty-first century, and to ensure that this vision informs evolving Army research and development requirements. The report describes the workshop design and execution, identifies emerging issues and insights, and recommends improvements for future technology workshops. The report is intended for those who may influence or are influenced by operational medical support to the Army After Next and the Army Transformation, including medical professionals as well as policymakers.

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CONTENTS

Preface	iii
Figures	ix
Tables	xi
Summary	xiii
Acknowledgments	xxi
Acronyms	xxiii
Chapter One	
INTRODUCTION	1
Background	1
Effect of AAN on Army Medicine	3
Army Technology Workshop-99 Objectives	3
Workshop Structure	4
Medical Functional Panel Areas of Focus	5
Technology Panels	6
Workshop Process	7
Functional Panel Process	8
Technology Panel Process	9
How This Report Is Organized	11
Chapter Two	
MEDICAL FUNCTIONAL PANELS: RESULTS	
AND ASSESSMENTS	13
Medical Informatics/C4ISR	14
Promising Technologies and Functions	14
Issues	15

RAND Observations and Discussion	17
CSS/Evacuation/Hospitalization	17
Promising Technologies and Functions	17
Issues	20
RAND Observations and Discussion	22
Areas Warranting Further Investigation	24
Disease	26
Promising Technologies and Functions	28
Issues	28
RAND Observations and Discussion	30
Nonbattle Injury	32
Promising Technologies and Functions	32
Issues	33
RAND Observations and Discussion	37
Battle Injury	39
Promising Technologies and Functions	39
Issues	42
RAND Observations and Discussion	44
Areas Warranting Further Investigation	45
Chapter Three	
MEDICAL TECHNOLOGY PANELS: RESULTS	
AND ASSESSMENTS	47
Medical Advanced Technologies	47
Promising Technologies	48
Issues	48
RAND Observations and Discussion	49
Military Operational Medicine	50
Issues	50
	51
RAND Observations and Discussion	
Infectious Diseases	52
Infectious Diseases	52
Infectious Diseases	52 55
Infectious Diseases	52 55 55
Infectious Diseases	52 55 55 56
Infectious Diseases	52 55 55 56 56
Infectious Diseases Promising Technologies and Functions Issues RAND Observations and Discussion Areas Warranting Further investigation Medical Chemical/Biological Defense Promising Technologies and Functions	52 55 55 56 56 57
Infectious Diseases Promising Technologies and Functions Issues RAND Observations and Discussion Areas Warranting Further investigation Medical Chemical/Biological Defense Promising Technologies and Functions Issues	52 55 56 56 57
Infectious Diseases Promising Technologies and Functions Issues RAND Observations and Discussion Areas Warranting Further investigation Medical Chemical/Biological Defense Promising Technologies and Functions	52 55 55 56 56 57

Contents vii

Chapter Four	
IMPROVING THE WORKSHOPS	61
Concept for Medical Technology Workshops	61
Technology Workshop Structure	62
Deriving Future Operational Capabilities	63
Force Integration	67
Chapter Five CONCLUSIONS	69
Appendix AMEDD AFTER NEXT TECHNOLOGY WORKSHOP-99—	
PANEL OBJECTIVES	71
Bibliography	79

FIGURES

4.1	Medical Systems as Syntheses	62
4.2	Force Integration Seminar	68

TABLES

	Deriving Medical Support Missions from AAN	
	Missions	64
	Deriving FOCs from Future Medical Missions	66

SUMMARY

OVERVIEW OF ARMY MEDICAL TECHNOLOGY WORKSHOP (MTW-99)

This weeklong workshop focused primarily on identifying those portions of the Army's Medical Science and Technology Investment Strategy, principally Basic Research (6.1) and Applied Research (6.2) investment areas, that are essential to ensure that the Army will have the required medical capabilities to support the Army After Next (AAN) in 2025. The goal of the Medical Technology Workshop 1999 (MTW-99) was to support Army efforts to make the appropriate technology acquisition decisions by developing medical solutions for military requirements to protect and sustain the force. MTW-99 focused on four specific objectives to attain this goal:

- Determine new or refine existing medical and nonmedical technologies and systems to meet AAN-era force health protection capability requirements.
- Determine the feasibility and affordability of developing and fielding medical systems in support of AAN-era force health protection capability requirements.
- Develop medical input for the Assistant Secretary of the Army's (Acquisition, Logistics, and Technology) Technology and Materiel Game.
- Develop materials for use in the AAN and AMEDD After Next series of wargames and franchise events.

The workshop was divided into two types of panels: functional and technology. In the main, the functional panels focused on future operational capabilities (FOCs) and how proposed medical systems would satisfy their needs. The technology panels concentrated on exploring the investment and execution implications for the Science and Technology programs to acquire the capabilities necessary to support AAN-era Hybrid Forces.

INSIGHTS

RAND analysts developed a number of insights through their participation in the workshop. These insights and, in some cases, recommendations from the analysts, are keyed to the panel as follows.

Functional Panel Insights

Medical Informatics/C4ISR. Given the explosion in information technology, the ability of the Army (or DoD) for independent development of nonmilitary specific applications is doubtful. The AMEDD must exploit opportunities to leverage the work of others in this arena.

CSS/Evacuation/Hospitalization. It is now becoming clear that medical support will not only be a challenge for the AAN, it may also shape AAN doctrine. AMEDD must continue its involvement with the AAN process, including active and aggressive participation in operational planning at the commander in chief (CINC) level, both in the near and long term. Ensuring the ability of medical units to support a highly mobile force will call for force protection assets from warfighting units and the ability for rapid stabilization, evacuation, and treatment of potentially high numbers of casualties. If a paradigm shift is not realized conceptually and technologically concerning the simultaneous treatment and evacuation of stable and nonstable battle casualties, medical support could become the major limiting factor of AAN doctrine. Further, the AMEDD should investigate more closely requirements and solutions for dealing with mass casualties among both combatants and noncombatants in war or other military operations.

Nonbattle Injury. The AMEDD should incorporate personnel with high-level expertise in the specific areas targeted for technical development in this area. These areas include database development and management; data compression; data processing to develop predictive models, sensory measurement, and processing; communications; power technology; and neuroscience. Although involvement of such top experts may appear costly, under discussion is the best direction of millions of research dollars. To miss key cost-saving or performance enhancing technologies or to spend large sums on unpromising or obsolete technology because of failure to involve such individuals clearly has higher potential cost both in dollars and in future capability of the AAN.

Technology Panel Insights

Medical Advanced Technologies. DoD has a pressing need for the development of a unified information architecture for all medical activities. This architecture must adapt easily to new technology and be open and be secure. It should handle the collection, management, storage, fusion, mining, and transmission of medical data at all echelons of medical care.

Infectious Diseases. DoD needs to maintain an extremely active presence in research, science, and technology related to infectious diseases. Many of the issues in this area that are essential for military operations hold no interest for the commercial sector because they offer such a poor return on investment. This active presence requires a cadre of scientists with skills in microbiological (virology, bacteriology, and parasitology), clinical investigation and field studies of infectious diseases (internists, infectious diseases specialists and pediatricians), and vaccine and drug development and immunology. Academia encourages in-depth expertise in narrow areas, while military research encourages broad-based expertise in infectious diseases. The military, therefore, is much better equipped to respond to new and emerging threats (in conjunction with the Centers for Disease Control and Prevention [CDC]). Consequently, it is essential that the military invest in the next generation of military scientists in this field. Increased attention should be paid to patient (soldier) acceptance of new vaccines and pharmaceuticals to ensure force compliance and recruitment.

Medical Chemical/Biological Defense. Threats in this area are evolving continuously, and advances in basic research, including immunobiology, molecular biology, and selection of appropriate surrogate animal models, are necessary to address them. If each genetically engineered biological agent is regarded as an emerging disease (which, in effect, each is), the value of a basic scientific ability to keep up with disease emergence is high. AMEDD must continue to invest in 6.1 and 6.2 biological research and explore ways to recruit and retain highly qualified scientists. AMEDD should also broaden its communications with other U.S. government agencies involved in chemical/biological defense research, and leverage these sources where feasible and initiate risk-based discussions among these agencies, DoD, and the FDA regarding the registration process for chemical/biological defense technologies.

IMPROVING THE MEDICAL TECHNOLOGY WORKSHOP PROCESS

In general, this workshop was well designed, well organized, and well executed. It identified a rather comprehensive set of medical and medical support technologies needed to support AAN-era military operations.

However, five aspects of the workshop could be improved: systems cards, participant skills, development of future operating capabilities, workshop structure, and force integration.

Systems Cards

The use of systems cards tends to focus the participants more on process (getting through the cards) than on substance.

Participant Skills

Few of the participants felt adequately qualified to assess the relative effect of increases or decreases in research funding in the technologies identified as critical. This suggests a more direct link between required future capabilities and technologies and altering the process to include participants with programming experience.

Future Operational Capability (FOC) Development

Required future medical support missions must drive the capabilities generation process. The FOCs provided to the workshop participants provide examples of how capabilities should be written. Capabilities statements should not suggest systems to achieve them. Capabilities should be stated in terms of *attributes required* of the medical support force to accomplish the mission. There should be no reference to specific medical or medical support systems that might achieve these capabilities. By including systems in such a list, some technologies may be overlooked.

Workshop Structure

The medical technology workshop is essentially a brainstorming session. For brainstorming sessions to be productive, workshop planners must produce an environment that encourages the free flow of ideas. This means no preconceived notions of the "correct" medical solution and no technological "pet rocks." Seminar participants are a significant part of the input mix. The military medical personnel must be capable of articulating the desired medical support capabilities, and the medical doctors and scientists must be chosen for their expertise in the requisite technologies. A structure likely to prove successful has the following attributes:

- Small. The number of participants at any one group should be small: five to 10. Large groups tend to produce one or two individuals who monopolize the meeting and tend to intimidate lessforceful participants.
- Short. All meetings should be scheduled for one morning only. It is difficult to remain creative, innovative, and focused for much longer than that.
- **Focused.** Each session should focus on two or three *related* capabilities. This allows seminar planners to group technologists by field of expertise.

Force Integration

Building on the medical technology workshops, force integration seminars address how the medical and medical support systems might be integrated within the future Hybrid Force. In some cases, medical systems can function only in the context of a fully deployed combat unit. Such is the case with the future combat medic. In other cases, the medical system is relatively independent of the combat forces. A rear area medical hospital, for example, might fall in the latter category. In either event, some form of integrating event needs to be conducted to examine how and where the future medical systems fit in the overall AAN-era Hybrid Force.

Participants at integration seminars should include Army operators familiar with Army doctrine and combat systems and military medical operational personnel. Given that the medical systems and medical support systems generated in the medical technology workshop are essentially military end-items with an operational concept for their use, the logical next step is to integrate them with operational concepts for future forces.

AREAS WARRANTING FURTHER ANALYSIS

This workshop was a useful exercise and yielded significant insights about future medical operational capabilities and technologies. The process also revealed several emerging areas of concern that warrant further analysis:

• The relationship between AAN concepts and the medical concepts to support them seems somewhat disconnected. The AAN Battle Force conducts high-tempo, dispersed operations and is inherently lethal, mobile, and survivable. The AMEDD concept designed to address the medical needs of the Battle Force hinges on evacuation of casualties and cutting edge technologies—particularly in the area of patient stabilization. This concept becomes risky when casualties—friendly, coalition, enemy, and civilian—reach moderate to high levels. Workshop participants expressed concern over the ability to support Battle Forces medically because of the difficulty of getting casualties to the appropriate level of medical care in a timely manner.

- The asymmetric threats facing both deployed forces and those in the continental United States (CONUS) preparing to deploy are serious concerns in the AAN era. Weapons of mass destruction (chemical, biological, and nuclear) have the clear potential to create mass casualties that the AMEDD and other agencies will have to address.
- Much of the FOC of the AMEDD depends on new or improved technologies being developed and fielded in sufficient quantities to address the medical needs of the force. Some of these are largely military-unique systems, e.g., the medical evacuation pod, and critical to the support of AAN era forces. Largely absent from the discussions at the MTW-99 was an assessment of hedging strategies in the event that critical technologies or systems do not materialize because of scientific or funding limitations.
- The AMEDD research community is aging, and it is difficult to attract promising young investigators. This situation has important implications, because many of the research areas these researchers deal with hold little interest for commercial laboratories but are critical to military operations.

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ACRONYMS

AAN Army After Next

AOR Area of responsibility

AMEDD Army Medical Department

BW Biological warfare

CDC Centers for Disease Control and Prevention
CECOM Communications and Electronic Command

CINC Commander in chief

C4ISR Command, Control, Communications Com-

puters, Intelligence, Surveillance, and Recon-

naissance

CLIA Clinical Laboratory Improvement Amendment

COTS Commercial off the shelf
CSA Chief of Staff of the Army
CSS Combat Service Support

CW Chemical warfare

DAMIS Deployment Area-Specific Multicomponent

Immunization System

DARPA Defense Advanced Research Projects Agency
DCSDOC Deputy Chief of Staff for Doctrine (TRADOC)

DNBI Disease and Nonbattle Injuries

DoD Department of Defense
DOE Department of Energy

DOW Died of wounds

EMP Electromagnetic pulse FCM Future Combat Medic

FDA Food and Drug Administration
FOC Future Operational Capability
FUE First Unit Equipped (date)

HHS Department of Health and Human Services

Hybrid Force A force consisting of Army of Excellence, Army

Transformation, and AAN-era units

IND Investigational new drugs

ISR Intelligence Surveillance and Reconnaissance

KIA Killed in action

LOC Line of communication

MAT Medical advanced technology MOM Military Operational Medicine

MRMC Medical Research and Materiel Command

MTW Major theater war

NBC Nuclear, biological, and chemical

NBI Nonbattle injury

NGO Nongovernmental Organization

OSHA Occupational Safety and Health Administ-

ration

PGW Persian Gulf War

POM Program Objective Memorandum

RAMVIT Rapid Manufacture Vaccine

SWG Spring Wargame

TLS Training, Leadership, and Soldier Support
TRADOC U.S. Army Training and Doctrine Command
USAMRIID U.S. Army Medical Research Institute for

Infectious Diseases

WMD Weapons of mass destruction

INTRODUCTION

BACKGROUND

The Chief of Staff of the Army (CSA) initiated the Army After Next (AAN) project, led by the Training and Doctrine Command (TRADOC), in February 1996. The project's goals are to link Army XXI to a long-term vision of the Army extending several decades into the next century and to ensure that this vision informs Army research and development (R&D) requirements. The Army's Deputy Chief of Staff for Doctrine (DCSDOC) requested that RAND support TRADOC in this effort.

To ensure that medical capabilities, programs, and systems are integrated with the AAN program and the future Army, the U.S. Army Medical Department (AMEDD) has been actively involved in the AAN project. AMEDD personnel have participated in the FY 1999 series of AAN games, conferences, and workshops, serving as players and as franchise sponsors of events focused on AMEDD issues and goals.

Results from the AMEDD After Next Wargame '98, AMEDD participation in the Spring Wargame '99, and the AMEDD After Next Capabilities Workshop, along with the current Science and Technology investment strategy, provided the framework for the Army Medical Technology Workshop (MTW-99), conducted at Booz-Allen, Hamilton, Inc., in McLean, Virginia, June 14–18, 1999. The principal basis, however, for the technology requirements considered in the workshop was current and future systems.

The workshop focused on identifying those portions of the Army's Medical Science and Technology Investment Strategy, principally Basic Research (6.1) and Applied Research (6.2) investment areas,

that would be essential in ensuring that the Army will have the required medical capabilities in the AAN time frame. Identification of these capabilities provided the impetus for revising the investment strategy to promote support for the enabling and crosscutting medical technologies needed in the 2025 time frame.

Although this workshop focused on the medical technology issues involving support of AAN concepts, the insights from the effort bear directly on the Army's ongoing transformation efforts. The Objective Force units that played in the April 2000 Army Transformation Wargame employed operational concepts similar to those used by AAN maneuver forces. They conducted dispersed, high-tempo operations over vast operational distances. Additionally, the transformation effort explicitly focuses on reducing logistical (including medical) footprint in the operational theater. Clearly, many of the medical challenges that AMEDD dealt with in the game vis-à-vis AAN forces are present in the transformation forces, e.g., the requirement for forward resuscitation and stabilization of casualties, the need to deal with lengthy evacuation distances, the complexities of force health protection for rapidly deploying forces, etc. Thus, the insights from this game are directly relevant to solving the medical technology issues inherent in support of Army Transformation.

This report documents RAND's analysis of the MTW-99. It describes the workshop design, summarizes the major findings of the various panels, identifies the salient issues and insights that emerged during the workshop, and makes recommendations to improve future workshops. Some suggestions and recommendations are also made regarding specific medical technologies or functions. Because the main purpose of this report is to describe and comment on the MTW, these suggestions and recommendations are not meant to be definitive but instead are offered largely as subjects worthy of further inquiry, based on our observations of, and participation in, panel proceedings. This report is intended for those who may influence or are influenced by operational medical support to AAN and the Army Transformation, including medical professionals as well as policymakers. While medical terminology is unavoidable when discussing future medical technologies, we have attempted to provide lay explanations where they are essential to understanding the context of the workshop.

EFFECT OF AAN ON ARMY MEDICINE

Before continuing with the discussion of MTW-99, a few words about the relationship between evolving AAN and Army Transformation concepts (and insights from the Spring Wargames) and their impact on AMEDD concept development are appropriate. The operational concepts being developed for AAN and Army Transformation could have an enormous impact on the ability of the AMEDD to deliver medical care to AAN-era forces. These difficulties arise primarily from the dispersed nature of Battle Force operations and the depth and operational tempo of the projected battlefield. As part of the first day's presentations, a medical concept for supporting a Battle Force in action was briefed. Strong concerns were voiced about providing timely care to severely wounded soldiers, getting more than buddy aid to their location, and the long evacuation distances (and times) associated with widely dispersed Battle Force operations. Indeed, a number of participants in the workshop expressed doubts about the ability to medically support Battle Forces because of the difficulty of getting casualties to the appropriate level of medical care in a timely manner.

These concerns were based on an assessment of a Battle Force concept that assumes few friendly casualties because of the Battle Force's inherent survivability, mobility, and lethality. The task of providing medical support would increase dramatically if a Battle Force suffered more than very modest casualties—as it did during numerous engagements during the AAN Spring Wargames (SWG-98 and SWG-99). Additionally, the ability of the medical system to deal with the other types of casualties—enemy prisoners of war, refugees, etc. —that frequently occurred during the SWG-98 and SWG-99, were not discussed during the workshop.

ARMY TECHNOLOGY WORKSHOP-99 OBJECTIVES

The goal of the MTW-99 was to support Army efforts to make the appropriate technology acquisition decisions by developing medical solutions for military requirements to protect and sustain the force in the AAN time frame. This report focused on the first two of the four workshop objectives listed below:

- 4 Army Medical Support to the Army After Next
- Determine new or refine existing medical and nonmedical technologies and systems to meet AAN-era force health protection capability requirements.
- Determine the feasibility and affordability of developing and fielding medical systems in support of AAN-era force health protection capability requirements.
- Develop medical input for the Assistant Secretary of the Army's (Acquisition, Logistics, and Technology) Technology and Materiel Imperative Seminar Game.
- Develop materials for use in the AAN and AMEDD After Next series of wargames and franchise events.

WORKSHOP STRUCTURE

The workshop lasted four and one-half days (June 14–18). The first day was devoted to registration and orientation briefings (AAN "How to Fight"; AMEDD AAN Concepts of Operations; AMEDD Future Operational Capabilities; Overview of the Technology Materiel Imperatives Seminar Game; Medical Science and Technology Investment Strategy; and Workshop Process and Orientation).

The substantive part of the workshop occurred in two sessions. The first focused on five medical functional areas, or groupings of functions, deemed key to supporting AAN-era hybrid Army forces that cut across the entire spectrum of force health protection. The five functional areas examined were the following:

- Medical Informatics/C4ISR.
- CSS/Evacuation/Hospitalization.
- Battle Injury.
- Nonbattle Injury.
- Disease.

The second session focused on five medical technology investment areas:

Medical Advanced Technology.

- Military Operational Medicine.
- Infectious Diseases.
- Combat Casualty Care.
- Medical Chemical/Biological.

After each session, each panel briefed in a plenary session. The workshop concluded with a Senior Leaders Seminar the morning of June 18.

In addition to the panels, a White Team served as control and provided independent analysis of the workshop results, guidance, and administrative and operational support. The Independent Analysis Team also examined specific crosscutting issues, such as the Department of the Army initiative in technology provision to Training, Leadership, and Soldier Support (TLS).

Medical Functional Panel Areas of Focus

As noted above, the capabilities and technologies panels were the substance of the workshop, and each panel had its own focus, a detailed description of which is at Appendix A of this report. A summary of the areas of focus of each panel follows:

Medical Informatics/C4I Panel. This panel focused on using advanced communications, electronics, computers, and software and information technologies to meet the challenges presented in the AAN era.

Combat Service Support (CSS)/Evacuation/Hospitalization Panel. This panel had a broad charter to examine enhancements to all areas of health services, including medical, surgical, laboratory, and preventive medicine capabilities. Specifically, the panel focused on the capabilities required by medical units, from the most forward-deployed surgical detachments or aid stations through the echelons of care to CONUS fixed facilities. It was also charged to give special attention to identifying approaches that would reduce the "footprint" and sustainment requirements of deployed units.

Battle Injury Panel. This panel focused on increasing survivability and reducing morbidity in casualties in the AAN era by equipping

6

individuals—"buddies" and other first responders—with enhanced capabilities to reduce the killed in action (KIA) rate. Included was the identification of treatment capabilities that would extend the "golden hour" so that the KIA¹ rate does not increase despite delays in evacuation expected under many AAN operational scenarios.

Nonbattle Injury Panel. This panel focused on the identification of methods to enhance warfighter health and performance in the face of occupational or environmental health threats. It initially looked at those threats that would be created or magnified by military operations in the AAN era. The panel was asked to examine methods to increase physical and mental stamina and performance and to reduce occupational injury. It was also charged to consider solutions to the acute and chronic health risks imposed by environmental threats (heat, cold, or levels of toxic environmental pollutants). The panel considered monitoring of individual health and performance (e.g., Warfighter Physiological Status Monitoring efforts) and developing algorithms to predict, assess, or modify individual health and performance.

Disease Panel. The group concentrated on countering threats from disease-causing organisms, regardless of origin, whether endemic or spread by enemy action. The panel was initially assigned to explore the implications that warfighting in the AAN era might have on the relative priority of disease threats. It was also asked to address approaches that would reduce the time necessary to induce adequate levels of immunity, reduce side effects, and generally increase the availability and readiness of healthy warfighters.

Technology Panels

Medical Advanced Technology Panel. This panel focused on using advanced information and other technologies to meet the AAN medical challenges. The panel was asked to incorporate dominant battlespace awareness and full-dimensional protection into its dis-

¹The distinction between KIA and died of wounds (DOW) lies in evacuation; a casualty is considered DOW if he or she dies after reaching a medical treatment facility. DOW is also known as died of wounds received in action (DWRIA).

cussions. Its goal was to examine ways to leverage information to accomplish the primary military medical mission.

Military Operational Medicine Panel. This panel examined the protection of health and sustainment of military performance in the face of stresses that confront soldiers during deployment. Specifically, panel members were to examine research directed at understanding the physiology of the deployed soldier, the development of improved damage risk criteria to protect against materiel and environmental hazards, and the development of specifications, algorithms, and models for strategies and interventions to protect health and improve performance.

Infectious Diseases Panel. This panel focused on the prevention, diagnosis, and treatment of endemic and emerging infectious diseases with the potential capability for serious harm to military operational readiness. Diseases of principal interest were malaria, infectious bacterial diarrhea, and dengue fever.

Combat Casualty Care Panel. This panel focused on research programs that provide integrated capabilities for far-forward medical care that would reduce the mortality and morbidity associated with major battlefield wounds and injuries. The goals of the R&D efforts in this area are to extend the "golden hour" for treatment, to improve survival and minimize morbidity after life-threatening injuries, and to provide military medical capabilities for far-forward medical or surgical care of battle and nonbattle injuries. A primary emphasis is the identification and development of medical techniques and materiel for early intervention in life-threatening battle injuries

Medical Chemical/Biological Panel. This panel examined technologies designed to preserve combat effectiveness by timely provision of medical countermeasures in response to joint service chemical warfare requirements and to provide medical countermeasures for biological warfare agents.

WORKSHOP PROCESS

The functional and technological panels both operated under the processes described below.

Functional Panel Process

The purpose of the functional panels was as follows:

- To review and analyze the offered systems with respect to their ability to support the force health protection needs of their functional areas for AAN-era Strike and Battle Forces and the AANera Hybrid Force.
- To identify alternative systems or technological approaches to support the force health protection needs of their functional areas for AAN-era Strike and Battle Forces and the AAN-era Hybrid Forces.
- To modify the system cards (see below) for their panels, tailoring the description of functional characteristics, technological approaches, and investment areas to attain optimum benefit.

In conducting their deliberations, the functional panels were guided by the following set of questions:

- How important are the capabilities of the proposed solution to the requirements of medical (or warfighter) support needed by the AAN-era Battle and Strike Forces?
- How important are the capabilities of the proposed solution to the requirements of medical (or warfighter) support required by the AAN-era Hybrid Force (i.e., the total force that will include AAN-era Battle and Strike Forces, Force XXI, and Army of Excellence Legacy Forces)?

The primary tool the panels used in their deliberations were system cards. According the workshop materials, "Program goals will be described through the use of 'system cards' that provide system descriptions and capabilities for those systems being fielded in the program as well as additional systems not in the program but [that] may offer some new advantage to the AAN." System cards were descriptions of capabilities and underlying technological approaches to a particular solution set to meet the force health protection needs of the AAN-era Army. The cards contained the following information: system name, system description, system benefit, system

capability, system linkage (to the 13 FOCs),² technological investment area, and system enabling technologies.

During their deliberations, panel members were first to discuss the scope of their panel areas and how the systems described in their set of system cards fell within that scope. At that time, the panel could decide to add or eliminate any system. The functional panels then reviewed and revised system cards, identifying the three most important benefits and FOCs for each system they retained or added. At any time during deliberations, the panel was free to propose a new system that would meet a desired operational capability, and a new system card was constructed for that system. The panel then assigned a weight (1–10) to each system, based on the questions, noted above, that guided their deliberations. Finally, the panel developed a briefing, given at a plenary session, that identified issues and insights from their deliberations and prioritized the system cards considered.

Technology Panel Process

The technology panels focused on exploring the investment and execution implications for the Science and Technology programs of acquiring the capabilities described on the system cards for AAN-era Hybrid Forces. Specifically, the panels were tasked to:

- Review the present Science and Technology investment strategy.
- Determine the technical feasibility of systems in unconstrained and constrained resource environments.
- Review, validate, and recommend adjustments in cost-scheduleperformance of proposed systems.
- Propose alternative or additional enabling technical solutions.

Panel members were asked to discuss the scope of their panel areas and how the systems described in their set of system cards fell within

²The 13 "AMEDD After Next" FOCs were developed by the AMEDD After Next Capabilities Workshop held at the AMEDD Center and School in March 1999 and are listed in *The AMEDD After Next Technology Workshop '99 Workshop Guide* provided to all panel members.

that scope. At the same time, they were to review the system cards to identify significant inaccuracies and discuss any other system cards assigned to other panels for inclusion in their deliberations as appropriate. As with the functional panel process, panels could create new system cards.

During their deliberations, the panels were to discuss the feasibility of the technical approaches and assess the risks pertaining to cost, schedule, and performance of the system. Any information on the system cards could be modified by the panel, but the focus of the discussion was to be on the cost, schedule, and performance factors of the system and the associated risks in meeting the system goals. In concluding their deliberations, the technology panels were asked to consider the following set of questions:

- If the Army did not invest in R&D for the system's enabling technologies, what is the likelihood that the system capabilities would be available from industry or other government organizations?
- Given the panel's knowledge of the regulatory and technical challenges inherent in the advanced development of this type of system, is the proposed Milestone 1 date reasonable to achieve a First Unit Equipped (FUE) date prior to 2025?
- Given the current investment profile in the relevant technology investment areas, is the risk of achieving the projected schedule for availability high, low, moderate, or uncertain?
- Given that a 10 percent increase in the panel's total investment profile during the Program Objective Memorandum process (POM 02-07) were available to supplement the relevant technology investment areas, would the risk of achieving the projected schedule for availability be high, low, moderate, or uncertain?
- Given a 10 percent decrease in the panel's total investment profile during POM 02-07, would the risk of achieving the projected schedule for availability be high, low, moderate, or uncertain?
- If unfunded in the current funding profile, what is the amount of funding (by technology investment area) during POM 02-07 that

- Optional: In relation to the cost of today's fielded solutions, is the procurement cost likely to be higher, lower, about the same, or uncertain?
- Optional: In relation to the cost of today's fielded solutions, is the sustainment cost likely to be higher, lower, about the same, or uncertain?
- As with the functional panels, the technology panels briefed their results at a plenary session.

HOW THIS REPORT IS ORGANIZED

The next two chapters present the results of the two panel groups—functional and technology. Each summarizes the areas the panels considered, the technologies and functions viewed as important, the issues the panel thought the technologies and functions raised, and the observations of the RAND analysts on the panel deliberations. As the functional and technology panels were associated by subject as well as by participants, some of the technologies and functions discussed in Chapter Two are further elucidated in Chapter Three, as they were during the technology panels. Chapter Four discusses some suggested procedural and structural improvements for the workshops. The last chapter presents our overall conclusions.

Chapter Two

MEDICAL FUNCTIONAL PANELS: RESULTS AND ASSESSMENT

This chapter presents the RAND analysts' observation of the Medical Functional panel deliberations. RAND observed and reported on the following panels:

- Medical Informatics/C4ISR.
- CSS/Evacuation/Hospitalization.
- Disease.
- Nonbattle Injury.
- · Battle Injury.

For each panel observed, the chapter presents a brief summary of the areas considered, a discussion of what the panel saw as promising technologies and functions, a summary of the panel discussion on a variety of issues, and summary observations of the panel discussions by RAND analysts. In reporting the issues the panel discussed, we make no attempt at completeness. Rather, we focus on issues that strike us as important but that were raised but not discussed or were discussed only briefly. Thus, this report complements the transcripts of the panel deliberations. However, this does not imply that the issues discussed here are more important that the ones discussed extensively by the panels.

MEDICAL INFORMATICS/C4ISR

This panel focused on using advanced computing and communications to meet the challenges of the AAN era. This focus included both the hardware and software needed to support the collection, management, fusion, and distribution of medical information and the integration of the various components into mission-specific systems. Computer-based training of individuals and units was also considered.

Promising Technologies and Functions

Medical informatics draws on a wide range of current and emerging computing and communications technologies. Among those identified by the system descriptions were the following:

- Modeling and Simulation. A biological or physical system model mirrors the effects of changes in the modeled system, thereby facilitating understanding of the real system. Medical applications include the modeling of the behavior of human organs or the simulation of a surgical operation. Models of this sort can be very useful for education and training.
- Network Management (MEDNET). The transmission of medical information through a supporting network is critical to delivering care on the AAN era's widely dispersed battlefield. These networks can range from small local area systems supporting only a handful of nodes to national and international networks connecting tens of thousands of users. The performance, reliability, and integrity of such networks are essential characteristics of the information infrastructure, and therefore their efficient management is critical. In the AAN era, these networks will ride on the general C4ISR AAN network being developed by the Army's Communications and Electronics Command (CECOM). The medical community networks will be provided with "service-ondemand," that is, no dedicated communications paths will support MEDNET, but rather a path will be made available when required, thus creating a *virtual* dedicated network.
- Human-Computer Interface. Traditionally, humans use a keyboard to communicate with a computer. More recently, com-

puter voice activation techniques and cursive script have been used. Further research is needed to develop interface technology that will enable humans to interact more effectively with computers. Research needs to focus on the way information about the human user is delivered to the computer, how information about the computer is delivered to the human, and how to customize inputs and outputs to an individual user or application.

- Data Collection and Management. The accuracy and integrity of medical data as it passes through the medical information systems is critical to military health care. In the medical arena, the accuracy of the input data and its integrity as it passes through an information system are particularly important.
- Decision Support Systems: Forward-deployed medics depend on automated decision support systems for advice in treating casualties. Because of the operations tempo on the battlefield and because the primary care-giver will not be a physician, these systems must be simple, e.g., a stoplight chart. These systems have several components: a language for the user to communicate with the system, a software system to process user requests, and a body of knowledge about the relevant problem domain. Medical applications include systems designed to support health care staff in decisions concerning diagnosis and therapy. For example, a system might help a physician decide on the most effective diagnostic imaging technique to use in a given situation.

Issues

How Do We Mitigate the Problems of Melding Service and Coalition **Views on Future C4ISR Work?** The opinion of some panel members was that, at present, a number of incompatible medical information systems do not work well together, most notably digital medical records. Such records need to be stored in a database. Storage format varies from system to system, and it is often very difficult, or even impossible, to convert from one format to another. For example, one particular format may have required fields that are absent from another format, so the conversion is impossible unless someone adds those required fields by hand. If open system concepts were used, then all data could be presented in the same standardized format, which would ameliorate this problem.

As the common C4ISR architecture matures, the medical community should ensure that commonly agreed-on systems are designed and that network requirements for these systems are communicated to the CECOM communications systems developers.

It is not clear that the current information systems can effectively evolve into the open systems desired in the future. Many components of current systems include proprietary software that only runs on a limited number of computing platforms. If the medical community is to plan for the AAN era, it might consider redesigning the relevant architecture so that modern programming concepts can be built in from the start. It would, however, take considerable leadership over several years to develop such an architecture.

How Do We Adapt the Ever-Changing Information Technology to Match Human Capabilities? How Do We Avoid Information Overload? As more information is digitized, humans are likely to be swamped with so much data that it becomes impossible to use the data intelligently. A possible solution involves developing or acquiring many capabilities, including tools for information displays, for searching large amounts of data, and for filtering out spurious information. The limitations imposed by the small displays of handheld devices also need to be considered because such devices most likely will be used increasingly in the years ahead.

The medical community is not unique in seeking efficient methods to mine large amounts of data. Other communities are currently devoting considerable resources to the problem. One solution is a browser resembling those of the World Wide Web that efficiently guides the user through the data maze.

How Can the Potential Delays in Fielding Information Management/Information Technology (IM/IT) Systems Be Minimized? It often takes too long to field a medical information technology because of delays introduced by the Food and Drug Administration (FDA) approval process required for all new medical systems. This process, which was designed more for reviewing conventional medical developments, such as drugs, is not well suited for such advances as telemedicine, where the development process involves many milestones before a successful product is launched.

To reduce the time it takes to field a new IM/IT system, it might be necessary for system developers to collaborate with the FDA during every step of the development process so that any concerns can be dealt with as early as possible.

RAND Observations and Discussion

The promising technologies mentioned above are under active development in the commercial arena. Existing and future commercial investments in these technologies are likely to represent substantial investments. The two areas in which Army investment could be beneficial, however, are in the integration and adaptation of commercial off-the-shelf (COTS) components and products into AMEDD systems, and the development of system-specific software to support these systems. The Department of Defense in general and the Army in particular are no longer in a position to take a leading role in the funding of any future generic information technology development. By careful negotiation with technology developers, they may be able to ensure that AMEDD needs are met.

CSS/EVACUATION/HOSPITALIZATION

This panel focused on capabilities required to provide medical support to the AAN at all echelons of care. The panel's charter encompassed all areas of health services and sustainment and reduction of medical units' "footprint." However, the discussions primarily involved far-forward care (echelons I and II) and evacuation capabilities as well as the possibility of employing some characteristics of echelon III-type care farther forward.

The panel consensus was to focus on principles identified as most important during the AMEDD After Next Wargame in November 1998. These principles were Total Situational Awareness, Resuscitation, Stabilization, and Evacuation.

Promising Technologies and Functions

The most promising functions and supporting technologies identified and discussed by the panel included those that would seem to provide the best support to the principles mentioned above in general and technologies related to stabilization in particular. The consensus of the panel was that technologies were required to intervene in the "golden hour" when a soldier first becomes a battle casualty. The focus of the proposed functions and technologies was to provide hemostasis by a variety of means, including enhanced oxygen delivery and means to stop bleeding noninvasively. The panel also concluded that if far-forward care is to be an important component in the support of AAN doctrine, then more-mobile and rugged shelters will be required for forward surgical teams. After combining many of the system cards into single categories based on requirements (a weakness of proposing isolated technological concepts to fill needs), the panel reached consensus on the five most important systems requiring further investment to support the AAN Battle Force:

- Evacuation and en-route care assets. As discussed below, agreement was reached that the depth of the AAN-era battlefield will necessitate some care during evacuation; however, the level of this care was not widely agreed on. These assets include ground and air vehicles as well as some modular concept of evacuation platforms, from patient pods to suites of pods.
- Oxygen delivery enhancers. In the "golden hour" (or "golden ten minutes" as some panel physicians pointed out) after a soldier is wounded, the body suffers from low levels of oxygen because bleeding diminishes the body's capacity to carry oxygen. "Oxygen delivery enhancers" refers to the need to restore oxygen to a casualty's organs in a variety of ways, including methods to reduce metabolic oxygen requirements (the demand) and methods to increase oxygen delivery (the supply) through such technologies as artificial blood or hemoglobin (the molecule in red blood cells responsible for carrying oxygen). In addition to saving lives, this capability would greatly reduce the footprint of blood management, for which current logistics requirements are very high. While this item was ultimately labeled "oxygen deliv-

¹The term "golden hour" is more appropriate when discussing the timing of resuscitative care for blunt-trauma victims and does not accurately convey the urgency of care required for penetrating trauma more characteristic of combat casualties (see Ronald F. Bellamy's chapter, "Combat Trauma Overview" in *Textbook of Military* Medicine, Part IV, Surgical Combat Casualty Care, 1995, pp. 1-42). The term is used here, and was used during the workshop, because it has come to signify the necessity for rapid care and evacuation of combat casualties.

ery enhancers," the theme was really the concept of simultaneously improving the ways to restore the function of a healthy circulatory system while reducing the need for such a system. In addition to blood technologies, therefore, such a system may include a "casualty salvage system," designed to slow metabolism by chilling the body organs with fluid. This last technology was not well received by the panel as feasible.

- Modular oxygen generation system. When medical units deploy, they must carry tanks of oxygen for patient care. The importance of this oxygen supply and use was debated by the panel, but it was generally concluded that a large oxygen demand is easily conceivable for AAN forces (discussion points included the historical use of medical oxygen and the actual requirements and benefits). It was pointed out in the panel that enough oxygen canisters to support a major theater war (MTW) might not even currently exist, and the logistical requirement to support an army with oxygen tanks is enormous. Therefore, it was concluded that a point-of-care oxygen generation system would be required to reduce the medical footprint, sustain performance, and reduce mortality. The challenge for the AMEDD After Next is to develop a system that is rugged and easily portable. Current oxygen generation systems are very cumbersome and require large amounts of power to operate.
- Field-portable noninvasive diagnostic imaging and therapeutic hemostatic system. Again, this capability underscores the need to stop bleeding as quickly as possible. This system is based on a technology resembling ultrasound (though not necessarily ultrasound) that would enable a care-giver to locate a bleeding artery or vessel and patch it.
- Lightweight shelter and associated items of equipment. The system card originally considered to meet this requirement included specifications that the panel did not feel were appropriate (such as a requirement for a 4,000-pound forklift to transport the shelter). The panel envisioned a multipurpose, small shelter, which is transportable on a small future tactical vehicle (e.g., the size of a Humvee). Such a shelter would be easily and quickly assembled or disassembled, and it would provide protection for far-forward care. This concept is discussed below.

For What Types of Injuries Must the AMEDD After Next Plan? The process to determine AMEDD After Next capability requirements is hampered by the lack of a casualty assessment for AAN doctrine, including the types and numbers of expected combatant and noncombatant casualties. The panel recognized a need for models that will determine the effect of new weapons, technologies, and operations on the types and severity of injuries. For example, what types of injuries are expected from directed-energy weapons? What role will future body and vehicle armor play in casualty production? Dif-

ferent operational theaters may also affect casualty production. For example, urban warfare may produce more eye injuries stemming from such secondary projectiles as cement fragments, yet current deployable medical units have very limited capability for treating these injuries.

Casualty data from SWG-99 were not referenced in the discussions although it may have been useful. However, more definitive model-

Casualty data from SWG-99 were not referenced in the discussions although it may have been useful. However, more definitive modeling is clearly needed to plan most beneficially for the treatment of AAN casualties while reducing the medical footprint. With accurate casualty predictions, the medical logistics community can plan better packages tailored to supporting specific operations. If such modeling is performed early, the results can also effectively direct R&D efforts for AMEDD After Next technologies.

How Mobile Can Future Medical Forces Realistically Expect to Be? The AAN doctrine includes speed as a basic requirement. Much of the panel's discussion centered on increasing the mobility of far-forward care to support a rapidly deploying and highly mobile force. For example, the panel considered a highly mobile, easily deployable shelter for far-forward care (e.g., forward surgical teams) a high priority. The panel consensus was that the current, level-III carecapable, Deployable Medical System is not sufficiently mobile to meet the AAN support requirements. In fact, some current units have procured commercially available lightweight shelter systems for increased deployability and mobility.

One physician on the panel cited a study comparing morbidity and mortality of casualties provided battlefield treatment (e.g., from a medic) with those that were not. The conclusion was that nondefinitive battlefield care was largely immaterial (in a strictly clinical sense²) and what really mattered was the timing and effectiveness of higher-level *definitive* care given. In this case, far-forward definitive care seems to be the best solution for saving battle injury casualties when lines of communications (LOC) are long, as they are in AAN scenarios. However, the ability to provide such care seems unlikely to result in the "greatest good for the greatest number," when realistic estimates of the care capacity of medical units designed to be highly mobile are considered. Such consideration is provided in the observations and discussion section below.

How Can the AMEDD Best Support the Dynamic AAN Battlefield? The panel consensus was that a combination of far-forward treatment and evacuation was required to support AAN medically. While much of the discussions focused on specific medical technologies to overcome long LOCs (oxygen delivery, hemostasis technologies), some attention was also paid to the operational concepts of far-forward care and simultaneous treatment and evacuation. The supposed difficulty or inability to provide medical personnel where and when needed led the panel, like other panels, to emphasize the importance of basic skills training. This emphasis may be an a priori reaction to the realization that evacuation will be difficult and far-forward surgical care challenging at best. It was recognized that other solutions are needed.

There may indeed be other solutions, including combining evacuation and treatment platforms. Such a solution would, on the surface, require a paradigm shift away from a doctrine of evacuating only stable patients. In reality, this paradigm shift occurs whenever U.S. forces are wounded in action. As a former combat-experienced division surgeon on the panel pointed out during a break in the panel deliberations, "at some point you either evac the guy as-is or leave him to die." As the practice of evacuating unstable casualties in extreme circumstances already exists, it would be beneficial to build capabilities around this practice. Some technological requirements to consider in developing this capability include the following:

²This discussion was exclusive of other important factors, including, for example, any potential psychological benefit to soldiers of knowing that immediate medical care is available on the battlefield. These factors warrant further attention in the context of determining the ultimate deployment of medical assets to support AAN.

- High-volume capacity, so that if a casualty is not being treated at a given time, he or she is at least still being evacuated.
- All-weather capability of the evacuation platform (whether ground, air, hover, etc.).
- Stabilizing technologies (such as gyroscopic stabilization) coupled with windshear/turbulence, etc., prediction and predictive, active vehicle suspensions to provide a reasonably stable platform on which to provide treatment.
- Technology to improve the stabilization of casualties for extended evacuation times, including those discussed in the panel (e.g., hemostatic agents).

The panel deliberations imply that the AMEDD should be involved in the development of emerging automotive and airframe technologies to influence their design in a direction which will support a simultaneous evacuation/treatment capability.

RAND Observations and Discussion

AAN presents a paradox for medical support. On one hand, a deep and dynamic battlefield with long—often unsecured—lines of evacuation means that evacuation assets can become quickly overwhelmed even in the absence of mass casualties. A reasonable response is to take treatment far forward, both in terms of medical assets and increasing the medical component of basic skills training. This response is based on the assumption (current doctrine) that only stable patients should be evacuated to definitive care facilities. On the other hand, far-forward care has very limited capability considering the trade-offs between providing care and maintaining appropriate mobility. Pushing care forward may limit the very mobility needed to support AAN concepts.

Consider a forward surgical team with two operating tables. This configuration benefits the first two casualties received, but the others might as well be evacuated by the time the surgeon gets to them. Add to this situation the likely need to move to a more secure location, and the far-forward surgical team is quickly overwhelmed. Such technology as improved mobility and medical capabilities may

provide some relief, but hospitals most likely will remain a CSS burden, especially with long, unsecure LOCs.

An underlying theme in this panel was mobility. The need to increase medical mobility is not unique to AAN, as evidenced by the many current infantry medical platoons that operate with "tailgate" medicine (employing rapid response treatment teams in lieu of formally established aid stations), a doctrine not formally taught at the AMEDD Officer Basic Course. However, the AAN battlefield will pressure medical units to be even more mobile to keep up with the Battle Force and for force protection in an asymmetric battlefield characterized by unsecured LOCs. The panel considered rapidly deployable shelters for forward-treatment (surgical) teams to be a solution. The reality, however, is that a medical unit is mobile only until it receives patients. Consider again a forward surgical team with two operating tables, able to set up and begin operations in 30 minutes. According to a panel physician with experience in combat operations, a realistic planning factor is two and one-half hours for each surgery. Six wounded soldiers would require that the forward surgical team hold ground for at least eight hours, including deployment time. Is it realistic to expect that a given area in the AAN battlefield will be secure for that amount of time? Postsurgical treatment and stabilization will also hinder the mobility of such a unit.

This panel's attention divided in most discussions between concepts of far-forward care and evacuation. Considering the difficulties in evacuation from an AAN Battle Force because of distance and air security, the panel deliberated under the tacit assumption that if AMEDD cannot provide far-forward definitive care (considering the difficulties of evacuation over long distances), then AAN doctrine cannot be supported. However, in some instances, these deliberations moved into a new direction of en-route care. This thinking would represent a new doctrinal approach for the AMEDD, but it received too little attention in the time allotted the panel. This concept may represent a "middle ground" between far-forward care and evacuating unstable patients. It can be provided en route to more definitive care (this concept recognizes that no evacuation platform will be stable enough for microsurgery, etc., but many less precise procedures can be performed). Though a definition exists for definitive care, the concept of evacuating to more definitive care puts it on

a relative scale. A possible scenario for AAN medical support is to employ evacuation platforms that also include capabilities to provide *therapeutic* care—for lack of a better term—during evacuation to *more* definitive care. Such a capability is a limiting factor for the support of AAN doctrine.

It is becoming clear that medical support will not only be a challenge for the AAN, it may indeed shape AAN doctrine. It is imperative that the AMEDD continue its involvement with the AAN process, including active and aggressive participation in operational planning at the CINC level, both in the near and long term. The ability of medical units to support a highly mobile force will call for force protection assets from warfighting units and the ability to rapidly stabilize, evacuate, and treat potentially high numbers of casualties. If a paradigm shift concerning the simultaneous treatment and evacuation of stable *and nonstable* battle casualties is not realized conceptually and technologically, medical support could become the major limiting factor of AAN doctrine.

Areas Warranting Further Investigation

Preventive Medicine. It was generally agreed that the goal of the AMEDD After Next technology development effort should be to provide "the greatest good to the greatest number" of AAN soldiers. It is puzzling, therefore, why preventive medicine requirements did not receive more emphasis, especially considering the considerable impact Disease and Nonbattle Injury (DNBI) has had historically. Prevention-oriented system cards were limited to some dental technologies, assessment of vehicular biomechanical hazards (jolt), and an electromagnetic vector repellence system (vectors are organisms that act as agents in the transmission of disease, e.g., Anopheles spp. mosquitoes, which are vectors of malaria). It should be noted that fundamental principles of sensory biology make the efficacy of the electromagnetic vector repellence system very unlikely (and the requirement to be undetectable is a significant challenge in its own right). While preventive medicine capabilities were considered by other panels, this panel could (and should) have included it in discussions of "total situational awareness" as well as the logistical burden of providing preventive medicine assets and evacuating and treating DNBI casualties. While the statistics can be controversial depending on total population size and other factors, it is undeniable that battle injury rates have been and most likely will remain quite low in comparison with DNBI, yet the capabilities focus of the panel was on stabilizing and evacuating battle injury casualties.

Mass Casualty Situations and Capabilities. It was shown during SWG-99 that mass casualty situations—of combatants as well as noncombatants—should be planned for, if not expected, in the AAN era. However, as discussed above, the panel did not focus on capabilities to deal with these situations specifically, such as logistical push packages or reachback capability specifically designed to provide the "greatest good for the greatest number." It is a characteristic of physicians to strive to provide the best definitive care for each patient, triage practices not withstanding. However, the AMEDD After Next may need to consider guidelines and supporting capabilities to provide a minimum level of forward care for mass casualty situations and to determine methods for rapid, high-volume evacuation to level III care facilities.

Operations Other Than War and Homeland Security. The AMEDD After Next will continue to perform missions in these areas as it does now, with support and sustainment requirements significantly different from those of warfare. The panel did not consider technologies or capabilities specifically in these areas, although these may be needs that require further attention.

Electromagnetic Pulse (EMP) Protection. It is likely that the AAN era will be characterized by asymmetric threats, including EMP and directed-energy weapons, as demonstrated during SWG-99. While some systems reviewed by the panel were identified by the requirement, "hardened against environmental hazards," EMP protection was not addressed directly. Currently the AMEDD relies on COTS supplies for much of its medical technology. In the highly technical AMEDD After Next, it is conceivable that EMP will be a major threat to these technologies. It would be worthwhile to investigate technologies to provide EMP protection retroactively (postmanufacture) for commercially obtained and developed technologies. It might also be valuable to investigate contingencies in the event of asymmetric attack, such as EMP. AMEDD After Next will rely on substantial amounts of technology for situational awareness (e.g., soldier-worn medical monitoring devices) as well as casualty care, and the degra-

26

dation of these technologies could be devastating without proper contingency planning and training.

DISEASE³

The Disease panel focused on ways to prevent and combat disease in the Army After Next. To achieve this goal the panel was presented with more than 30 technology cards, which dealt primarily with the prevention or treatment of specific diseases. The panel focused on vaccines to prevent disease but also discussed drugs for treatment and prophylaxis and other countermeasures.

The panel developed a number of alternative taxonomies. One taxonomy, based on the location of the soldier, was as follows: urban warfighter, tropical/jungle warfighter, desert warfighter, recruits during mobilization, and unique environments. Preventing infectious disease is particularly challenging because of the large number of potential endemic and biological warfare (BW) agents that may affect an operation. The panel recognized that these diseases can be categorized in many ways to simplify discussion, deliberation, and research, but all are ultimately artificial. Traditionally, diseases have been categorized by microbiological taxonomy as viruses, bacteria, or parasites. The panel recognized that the type of organism infecting a soldier is of little concern to the warfighter.

A second taxonomy was budgetary. Research to prevent endemic infectious diseases is funded separately from research on ways to prevent BW attack. Classification of diseases as endemic versus warfare-induced is useful from the funding perspectives. It also allows use of intelligence data to prioritize BW research for the agents most likely to be weaponized. However, from the point of view of a medic or physician confronted with an ill soldier to diagnose and treat, it makes little difference how the infection was acquired. Furthermore, with such highly transmissible agents as smallpox, the second and third waves of infection could better be thought of as an endemic disease threat. In other words, the original taxonomy is not useful once smallpox moves from the category of an

 $^{^3}$ RAND researchers were present for only part of this panel's deliberations and, therefore, cannot report on all of its work.

eradicated disease to one causing thousands of cases in an unprotected population.

A third taxonomy derives from the recognition that soldiers are at risk of different diseases depending on their stage of military life. For example, basic training can be interrupted by respiratory infections (influenza, adenovirus, and meningococcal infection). Deployed soldiers are subject to endemic infections present wherever they deploy. Injured soldiers may be susceptible to wound infections caused by antibiotic-resistant organisms. Returning soldiers may pose risks to homeland populations if they return with drug-resistant tuberculosis or gonorrhea or such highly lethal infections as those caused by Ebola or Marburg viruses.

The panel concluded that considering diseases by these taxonomies was not very useful. It thought that it might be more useful to look at the military operational scenarios referred to by the military leaders and discuss required technologies within the context of these scenarios. For example, if urban warfare is anticipated, infectious disease research might be directed towards diseases that occur in densely populated areas where sanitation may fail. Such diseases include louse-borne typhus, bubonic (flea-borne) plague, diarrhea, respiratory infections, dengue fever, West Nile encephalitis, and others. If jungle warfare is anticipated, research should be directed at prevention of diseases associated with jungle transmission. These might include malaria, yellow fever, diarrhea, Lassa fever, Ebola fever, Marburg virus, and other as-vet-unidentified agents. If desert warfare is anticipated, leishmaniasis, diarrhea, or even dengue fever might be studied. Warfare in other special environments might predispose soldiers to particular types of infection. Fighting in or near rural areas might be associated with Japanese encephalitis or Nipah virus infection. In forested areas, tick-borne encephalitis might pose a risk. In scrub areas, scrub typhus and hantavirus infections are known risks. Onboard a ship, tuberculosis and Norwalk virus might pose special risks.

The panel concluded that for purposes of determining an approach to specific military infectious diseases, a taxonomy based on the type of military operations anticipated might make more sense to CINCs and others concerned about the specific risks to deployment. The diseases, which might be targets of research at any given time, might vary, depending on the projected warfare scenarios. This conclusion led, in part, to the promising technologies and functions listed below and also to those of the Infectious Disease panel (see Chapter Three).

Promising Technologies and Functions

- BW multiagent vaccine system. This vaccine consists of DNA segments of known BW threat agents. When administered orally, these segments will induce immunogenic responses that protect the vaccinated soldier against the BW agents.
- Anthrax vaccine. This vaccine will have a reduced dosage schedule and reduced time to immunity as well as reduced reactogenicity. It will also protect against genetically engineered strains.
- Medical countermeasures to orthopox viruses. Countermeasures include both a vaccine and therapeutic, antiviral agents.
- Medical countermeasures against plague.
- BW agent immunomodulator.⁴ This broad-based immunomodulator can be administered prior to or immediately after BW attack to confer protection by enhancing nonspecific immunity.

Issues

The panel identified a number of important issues, including the FDA regulatory process, differing military and commercial incentives, logistical issues, liability and indemnification of manufacturers, side effects of drugs and repellents, and concern over the military's ability to maintain its trained expert scientific staff in these areas.

How Can Technologies Progress More Rapidly Through the FDA Regulatory Process? The panel recognized that this issue is particularly important for the development of countermeasures against BW and CW agents. It goes beyond the regulatory barriers and ultimately

 $^{^4}$ The concept behind the "immunomodulator" is that it broadly stimulates a person's immune system, which provides protection against a wide range of infectious agents, including BW agents.

relates to costs and risks borne by manufacturers, differing risk-ofuse calculations, and mechanisms for dealing with the requirements surrounding use of investigational new drugs (INDs).⁵ IND rules on informed consent and record keeping can pose significant barriers to use of some products in a military situation.

For a variety of reasons, it has proved difficult to get newly developed pharmaceuticals and vaccines from the laboratory to the field for use by the U.S. military. Although the requirements of FDA testing and approval are common to the commercial as well as military sectors. these requirements can be particularly problematic for products produced primarily for military use. Problems are encountered in development and FDA approval for preventive and treatment measures for BW, CW, uncommon infectious diseases, and other conditions for which naturally occurring high-risk populations are not available for testing of efficacy and for which experimental induction of risk would be considered unethical.

The panel recognized and noted that the FDA plays a vital and important role in guaranteeing quality in pharmaceuticals and medical devices. Among other areas, the FDA ensures the efficacy and safety of products, sets and enforces rigorous quality standards for the manufacture of pharmaceuticals, and inspects products for potency to be certain they measure up to prototypes.

The panel also noted that it was essential to the deployed soldier that medical products be of the highest quality. For example, FDA approval requires evidence of both safety and efficacy. While safety of drugs for such military uses as CW/BW protection can generally be assessed to the satisfaction of the FDA based on animal studies followed by human studies, assessment of efficacy is potentially problematic. There may be no population at "natural" high risk for exposure to the conditions the drug is intended to treat or protect against (for instance, lethal chemical and biological agents), in whom ran-

⁵For further discussion of IND rules and issues, see the RAND report, *Military Use of Drugs Not Yet Approved by FDA for CW/BW Defense: Lessons from the Gulf War* (MR-1018/9-OSD), by Richard Rettig. This report examines the history of the Interim Rule, adopted in December 21, 1990, that authorized the Commissioner of the FDA to waive informed consent for the use of investigational drugs and vaccines for certain military uses and examines how this authority was used for pyridostigmine bromide and botulinum toxoid during the Gulf War.

domized testing can readily establish efficacy. Furthermore, for highly lethal exposures (e.g., BW and CW agents), the prospect of experimentally subjecting persons to such exposures, in order to assess the possible protection from lethality conferred by prospective prophylactic or therapeutic agents, is ethically untenable.

RAND Observations and Discussion

The FDA regulatory issue became prominent during the Persian Gulf War (PGW), and botulinum toxoid (BT) vaccine serves as a case in point. Iraq has been reported to have botulinum toxin available and militarized, and the U.S. military goal was to inoculate all at-risk troops with BT vaccine to protect them in the event of BW attack with BT. However, the available pentavalent vaccine was not FDA approved, because evidence on human efficacy was not available and could not readily be obtained for reasons noted above. This vaccine instead carried IND status from the FDA. The FDA passed an Interim Rule, permitting the military to administer this vaccine without the informed consent ordinarily required of IND use in specific military operation involving combat or the immediate threat of combat. However, this led to charges that the military was "experimenting" on its personnel and that the policy enabled by the Interim Rule caused "many military personnel" to be "involuntarily subjected to the very risks that the requirement of informed consent is intended to protect against" and eventually to a new regulatory process to solicit public comment.6

Surrogate markers of efficacy have been sought, with the goal to enlist FDA approval based on indirect evidence of efficacy. Specifically, it has been suggested that coupled human and animal evidence would show enough efficacy to be acceptable. For example, evidence that a vaccine induces an adequate immune response (measures of antibody production) in humans, coupled with evidence that the transfer of such human antibodies to animals protects these animals from experimental aerosol exposure to lethal levels of botulinum toxin would be one option (Pendergast, 1997). If the pro-

⁶Petition to Repeal Interim Rule, 1996 (May 7), to Dockets Management Branch of

cess is indeed to be sped up, methods will have to be developed and agreed on with the FDA.

Moreover, because the nonmilitary and/or peacetime market for some such agents may be limited or negligible and potential liability high, pharmaceutical companies may not be anxious to undertake development or production, and ensuring adequate production to meet potential wartime needs may be difficult. Similar problems have arisen in the context of so-called "orphan drugs" (Haffner, 1992; Scharf, 1985).

The solutions to these problems are unlikely to be easy and will involve advanced science as well as creative flexibility in regulatory administration. However, if the military hopes to succeed in making needed vaccines and drugs available on a timely basis in the future, it clearly must devote significant time and resources to these issues. In fact, advances in technology will likely outstrip society's ability to develop and administer ways to regulate their development, which ultimately may result in slowed availability. In short, if attention is not paid to this issue, the military could find itself in the position of watching scientific advances happen at a fast rate while the regulatory process moves at a much slower one.

Almost no discussion occurred about patient (soldier) acceptance or compliance with the new technologies that might be developed. This is, however, likely an increasingly important issue and problem. Recently a small but growing number of personnel have refused to receive the anthrax vaccine. Furthermore, soldiers often do not take prophylactic medications as indicated. For example, in the Gulf War, some soldiers never took pyridostigmine bromide (PB) for protection against nerve agents, some stopped taking it, some reduced the dosage or schedule, and some took too much. In the past, similar problems have arisen with drugs to prevent malaria.

If methods to gain troop acceptance of drugs and vaccines (particularly with INDs) are not developed, this could become a major problem in recruiting and fielding a ready force in the future. Acceptance is more likely to be an issue in 2025 if American society is more aware of pharmaceutical side effects, has ready access to information and rumors through the Internet, expects a higher standard of health than may have been true in the past, and is less prone to taking orders without questioning them.

It would appear wise for the Army to consider investing significantly in new technologies to educate troops and gain their acceptance as well as in technologies to develop vaccines and drugs. For instance, technologies employing the Internet offer a few of many possible options. In addition to educational technologies, issues and technologies centered on what has come to be known as risk communication should be considered.

NONBATTLE INJURY

The Nonbattle Injury (NBI) functional panel focused on identification of methods to enhance soldier health and performance in the face of occupational and environmental threats, particularly those created or magnified by military operations in the AAN era. No specific, truly revolutionary technologies were discussed in the NBI panel, although technologies that need ongoing development were discussed, including database development and management, sensor technology, power technology, information transmission, and data processing and modeling.

Promising Technologies and Functions

Each of the following systems was considered for the Military Operational Medicine (MOM) technology panel, and more detailed description of these systems, as revised by that panel, is provided in the Medical Technologies section.

Strategies to prevent stress-induced casualties. This system includes organizational leadership strategies to optimize effective military operations; selection, monitoring, detection, and preventive measures for stress casualties; and provision to commanders of information on real-time health status. This system was felt to support the AAN-era forces through increased survivability, sustained performance under operational conditions, enhanced individual readiness and performance, and reduced morbidity.

- Strategies to improve physical task performance without injury. This system includes optimizing safety of task requirements; elimination of training injuries during accelerated physical training; and selection, monitoring, detection, and preventive measures for physical injury. Such a system would support the AAN forces through enhanced individual and unit readiness and performance, reduced morbidity, and sustained performance under operational conditions.
- Physiological status monitor for commanders. This system includes informing commanders of impending injury and performance deficits for individual soldiers, interfacing with Land Warrior technology, and predicting near-real-time and real-time physical and mental status of the soldier. This system supports the AAN forces through enhanced individual and unit readiness and performance, sustained performance under operational conditions, and increased survivability.
- Sustainment of performance in extreme thermal and hypoxic environments. This was seen to encompass extremes of heat, cold, and altitude, and the system includes methods for selection, monitoring, detection, and preventive measures for environmental injury, with some crossover development of preventive and treatment measures. This system supports AAN-era forces through sustained performance under operational conditions, increased survivability, and reduced morbidity.
- Total body biomechanical injury modeling. This system was considered to entail integrated biomechanical modeling to provide design criteria, training strategies, and task design guidelines; and maintenance and improvement of performance with new technologies as with baseline technologies. This system supports the AAN-era forces through enhanced individual readiness and performance, increased survivability, and reduced morbidity.

Issues

Will New Technologies and "Solutions" for Reducing NBI Incur Their Own Risks for Casualties and Performance Effects? "Solutions," including drugs/pharmaceuticals, devices, and materials.

designed to prevent one problem could produce unanticipated problems of their own. All drugs have side effects, and when drugs are given for prevention rather than treatment, the expected benefit is reduced because of the uncertainty regarding whether the "problem" being protected against would arise for a given individual. The lesser expected benefit must be weighed against the risks (and possibly costs) of the "solution," and risks are generally not fully known until a product has been fielded.

How Can Provider Knowledge Be Built In? As integrated sensing, data transfer, and data processing information systems are developed, incorporation of provider knowledge might provide a jump-start to the systems and reduce the losses associated with "reinventing the wheel." Strategies should be sought for incorporating provider knowledge into such systems as those that predict high risk of imminent stress injury, physical injury, or serious performance decrement, with the goal of directing interventions to mitigate these problems.

How Should Knowledge Be Managed in a Cyber-Rich Environment? With the advent of the Internet, cellular telephones, and other mechanisms of real-time knowledge transfer in which the validity of transmitted information may be highly variable, military personnel may be subjected to information and images that are conflicting, inappropriate, incorrect, or damaging. For example, contact with family members by cellular telephone (or email or future modalities) may be sustaining or alternatively may add to the cognitive and stress burden as significant family problems at home are unveiled. Information from the media and Internet may question specific wartime strategies or deride the entire wartime effort. A member of the NBI panel noted a specific unanticipated instance in which media led to untoward sequelae (an aftereffect of disease or injury) in one soldier in Grenada. He had done well psychologically following an injury; however, he developed an acute stress reaction on seeing himself on the television news, his seriously injured body loaded into an ambulance.

As additional studies better define factors that induce stress reactions, guidelines could be developed to help personnel and family restrict burdensome information transfer at times of high risk of cumulative stress. One of the recommendations of this panel is

directed toward developing strategies to identify stress risk factors, to align personnel to duties by risk resilience, to track cumulative risk factors for and physiological markers of stress, to develop models to predict likelihood of stress, and to develop interventions to reduce stress, prevent stress casualties, and ameliorate symptoms and performance decrements induced by stress. Inputs to predictive models could include family strife; family deaths, injuries, or other problems; and receipt of information contrary to wartime orders or doctrine. These inputs could determine the potential effects of these factors in isolation and through interaction with other stress casualty risk factors. This in turn could lead to recommendations to personnel and family regarding types of information transfer that might be guarded against during periods of high stress casualty risk.

How Can a Systems Approach to Technology Development Be Implemented in the AMEDD? Unless the efforts of multiple research teams developing different technologies are integrated, the efforts may be mutually incompatible. For instance, they may be based on different assumptions regarding types of power supply or may increase the burden of power transfer; they may require mutually incompatible or duplicative pieces of equipment; or their utility may rest on information systems designed in such a way that they are mutually unintelligible. The challenge is to ensure that project leaders are brought together as new technologies develop, particularly at the 6.2 and 6.3 stages of research (with progression from the pure science phase to the development phase) so that integrated and compatible systems are produced.

The incompatibility of computer systems has plagued medical systems and other information-rich arenas, as attempts are later made to merge information in incompatible databases. (More recently, increased efforts have been made to develop bridging technologies.) On one hand, the perils of independent system development are obvious. For example, one effort may produce a set of sensors to measure a soldier's status and relay the information to a command station (with information integration at the soldier or at the station), while another project, developed by an independent group, may design a protective "second skin" (or body armor) for full-time use, which would preclude use of the first system. Because these are each designed without reference to the other, the latter would prevent relay of signals from the former. On the other hand, early integration decisions could restrict innovations in each domain and result in a lesser technology ultimately gaining ascendance.

How Can Acceptance of Risks Associated with Biotechnology Be Forwarded? The development of new biotechnological intervention brings new concerns to soldiers, the public, and the media, yet these interventions could be deemed necessary to the success of the AAN. With reduction in infant mortality and death from infectious disease as well as the extension of the normative life span, death is increasingly an unaccepted outcome in our society. Moreover, as workplace, home, and recreational hazards continue to decline with increasing involvement of government agencies (such as the Occupational Safety and Health Administration (OSHA)); as medical practice continues to improve; and as the culture of litigation over injury or death becomes increasingly dominant in our society, injury and death are increasingly considered unacceptable consequences both in peacetime and in wartime. As strategies are developed to enhance soldier performance and to protect against potential battle injury, almost any risks from or adverse effects of such strategies may be scrutinized, even if the aggregate benefits are found to greatly exceed risks.

Acceptance of risk by society may depend on a perception of threat. Just as patients at high risk of death from a condition will accept more potentially dangerous interventions to reduce this risk, so a society may accept more risk to the soldiers, including family members in the service, when the perception of national threat is greater.

Indeed, in keeping with this reasoning in the military setting, risks of employing an intervention or technology should always be critically evaluated against a likely potential benefit. As (hypothetically speaking) the threat of attack with a certain technology or agent (for instance) is reduced, the potential for benefit from "preventive" measures directed to that technology or agent is reduced, and at some point the expected benefit no longer exceeds the anticipated risks. (As discussed above, sound assessment of the risk-benefit profile requires that sound information on these risks is available.)

Acceptance of some technologies will depend critically on the framework in which these modalities are couched. Thus, discussion of personnel selection based on individual characteristics (perhaps

including genetic testing, a potentially sensitive issue) may best be framed in the light of recusing personnel who have particular susceptibilities from duties that may be selectively harmful to them or aligning personnel to duties for which they are particularly resilient.

How Will Extreme Specialization in the AAN Force Affect NBI? The AAN is conceived to have specialized personnel each with selected duties, who are highly interdependent, working in small teams. The lack of redundancy may increase risk to all members of the team if one member is injured. Must all members be capable of taking on other team-members' assignments? If so, this could dramatically increase the cognitive burden and training burden, perhaps increasing risk of stress-related casualty.

In the battle scenario, if a team-member receives a battle injury and other team-members undertake medic functions, not one but at least two persons will be functionally stricken from the team, further devastating the ability of the team to carry out its mission and possibly increasing the risk of further injury.

What Additional Stresses May Be Incurred During Joint and Coalition Operations, and How Can These Be Managed? Such factors as language differences, differences in force preparation, cultural differences, training differences, and command differences produce new stressors that differ from one joint operation to the next and that may therefore be difficult to predict. One panelist noted that when U.S. command strategies were used with some coalition soldiers, they "did not work." When asked to amplify, another panelist noted that soldiers of some armies are less independent and need more direction than U.S. soldiers, for example.

The degree of control over selected stressors in joint and coalition ventures can be expected to be reduced. As joint ventures take place, personnel could be queried regarding stressors, so that these can be incorporated into stress risk prediction databases and their predictive power ascertained.

RAND Observations and Discussion

Based on the issues discussed by the panel, further examination may be appropriate in the areas of database development and management, data compression, data processing to develop predictive models from input data, sensory measurement and processing, communications technology, power technology, and neuroscience (to look into possible biochemical and neurobiological correlates of stress, fatigue, and performance, as well as for establishing biological and neurobiological proxies for potential harm from specific low-level chemicals or chemical mixtures).

Although some discussion of adaptive processing occurred, no explicit mention was made that the systems to be developed might be designed to have ongoing adaptive update capability (with periodic backup of functional systems to permit restoration of function in the event of information sabotage or system failure). That is, as new information comes in regarding physiological and other parameters and new information comes in regarding outcomes, the systems should continue to update the "weights," linking inputs to prediction of outcomes. Moreover, it may be necessary that systems be designed to permit addition of new inputs, to accommodate refinements in knowledge regarding predictive factors—factors new to the AAN setting and not anticipated in developing the system—as well as to accommodate potential changing relationships between predictors and outcomes in the changing warfare environment.

No discussion of information errors (e.g., input errors), corruption, sabotage, and information warfare protection took place. Instead, the emphasis of the panel was on computer database generation and analysis, computer-based decisionmaking and decision support, and on protective measures against information input errors, information corruption, or information sabotage. Problems associated with information errors may occur at the point of input, integration, or transmission.

These technologies may guide and determine leadership decision-making (potentially including when to rest personnel because of predicted impending stress or physical casualty or when to intervene with drugs, devices, or other safeguards to prevent thermal, cognitive, stress, or physical injury). Thus, an enemy could have strong incentives to damage or destroy the system, deceive the system with false inputs, or sabotage signal transmission or interpretation in some of these systems. This threat has several implications. One is that strategies, such as error-correcting coding, should be developed

and incorporated as part of the signal transmission system. Selected signals may be sent for the purpose of evaluating fidelity of transmission. A second is that cross-checking software should look for implausible inputs and outputs. On the information processing side, it would be desirable for data systems to have relative robustness and fault tolerance, termed "graceful degradation," so that if one or a few signals are amiss among many, the overall output will not be wholly different but will be only correspondingly degraded. (Neural networks are among the systems touted as having this property.)

BATTLE INJURY

The Battle Injury panel was asked to focus specifically on strategies to improve survival and reduce morbidity among casualties in the AAN. Strategies considered to achieve this goal include equipping individuals, those around them (buddies), and other first responders with enhanced capabilities to reduce the KIA rate. The focus of the group extended from the point of injury to the most-forward surgical detachment, and specific strategies considered include:

- earlier identification of injured soldiers;
- better supportive intervention in forward areas; and
- Improved evacuation from the site of injury to the most-forward surgical detachment.

Promising Technologies and Functions

The most promising functions and supporting technologies identified and discussed by the panel were those that supported the principles discussed above. As with the CSS/Evacuation/Hospitalization panel, the Battle Injury panel agreed that technologies were required to enable early intervention following battle injury, in what has commonly been known as the "golden hour" (although controversy regarding the specific time window was debated). The most important issues discussed were the support of hemodynamic functions and pulmonary gas exchange (generally, the circulation of oxygenated blood). The panel was committed to providing the resources to intervene safely in the most-forward care situations. As

a smaller set of categories and arrived at the following priority areas:

- Individual Health Status Monitor. This technology is particularly relevant to providing care at far-forward areas (echelons I and II), reducing the KIA rate, and providing the ability to give state-ofthe-art support across the full spectrum of military operations. This technology focuses on providing the following specific features:
 - A suite of miniature biosensors transparent to the wearer.
 - Detection and integration of physiologic data (e.g., core body temperature, activity, sleep status, blood pressure, hydration).
 - Data conversion to information for health care providers to assess physical and cognitive performance of soldiers.
 - Guidance for work/rest rotations based on physiologic assessments.
 - Detection of battle and other injuries.

It should be possible to phase in the Individual Health Status Monitor as increasingly sophisticated components become available. For example, it is now possible to measure oxygen saturation, blood pressure, and pulse. As newer sensors are developed that employ microtechnology, they may be added to the individual health status monitor.

- Warrior Medic. Successful implementation of this technology offers the ability for efficiently serving the far-forward care units (echelons I and II), providing state-of-the-art systems for a broad spectrum of military operations, and offering the ability to provide key aspects of hospital care in diverse, challenging environments. This technology offers the following key features:
 - Medic variant of the Land Warrior System.
 - Wounding of a soldier notifies the medic of the injury.
 - Physiologic data are transmitted to the medic's computer.

- Artificial intelligence recommends remote triage on casualties, sends the medic to the most appropriate casualty first, and then assists in diagnosis while recommending a course of treatment.
- Positioning allows the medic to identify the soldier's location, at the same time transmitting vital data.
- Advanced Hemostatic (bleeding control) Agents. This technology addresses one of the key areas for essential R&D to meet the AAN goals. The technology specifically addresses clearly recognized problematic battlefield treatment issues that will offer increased survivability, reduced morbidity, and more feasible delivery of medical supply and resupply requirements. Successful implementation of this technology will dramatically advance key functional issues related to patient treatment and area support, particularly far-forward timely medical interventions and improved ability to meet the blood supply needs on a dispersed battlefield. Components or variants that might be appropriate include the following:
 - Control massive or continuous bleeding through intravascular, internal, and external agents.
 - Intravascular agents: antifibrinolytic pharmaceuticals to enhance clot integrity and antihemorrhagic compounds activated by vascular endothelium (generally, these agents would be introduced into the bloodstream and from there affect blood clot formation and breakdown).
 - Internal agents: hemostatic foam or fluid that can be injected into body cavities to stop bleeding from penetrating trauma.
 - External agents: Sprays and bandages that coagulate and protect large areas of abrasion or avulsion (detachment of a body part).
- Optimized Small Volume Resuscitation Fluid. This technology complements the advanced hemostatic technology discussed above, and, as with the others, facilitates essential treatment in the far-forward areas of deployment and increases the ability to

provide necessary care at the casualty location. Specifically, although advanced hemostatic agents offer the ability to control bleeding more efficiently, when hemorrhage is not controllable through hemostasis, the need for fluid support remains. This technology offers the hope of providing necessary fluids for resuscitation in a format that facilitates delivery in the combat setting. Key components of this technology that are important include the following:

- Minimizing the volume of fluid required to prevent cardiac arrest and rebleeding while maintaining the viability of vital organs.
- Optimization with respect to electrolyte and metabolic substrate concentrations.
- Augmentation of hydrogen ion buffering and oxygen carrying capacities that support cellular function and organ viability.
- Extended duration of shock tolerance for extended periods, permitting survival during the lengthy evacuations anticipated for the AAN.
- Prebattle Medications. This technology addresses the need to provide better prophylactic support. It is broad in scope in that it addresses both physiologic and psychological support, increasing survival, reducing morbidity, and enhancing troop readiness and ability to cope with unique challenges of the battle setting. Successful achievement of this technology will reduce the risks associated with NBC threats; improve survivability related to endemic diseases; and decrease adverse impacts of stress on personnel at all levels.

Issues

How Can Physiologic Information Related to the Status of the Individual Soldier Be Provided to Medics and Leaders? Miniaturization of biosensors is clearly possible because it is already available in the health care industry (e.g., pulse oxymetry, cardiac monitors). However, the scope of this project is considerably broader, including

notification of injury, specific nature of injuries, assessment of physiologic status, and ongoing reporting of soldier condition. An underlying assumption is the requirement to obtain multiple pieces of information regularly with transmission to a base unit (e.g., Warrior Medic) that will interpret the findings. Furthermore, the construct of the system must be such that it does not burden the soldier.

Expert databases will be required to interpret findings. Because these proposed systems are new, if expert systems are to interpret physiologic data, am underlying database that guides decisions regarding health and disease must be created.

What Are the Implications of Developing and Employing Advanced Hemostatic Agents? There could be issues related to the development of such agents used as pharmaceuticals. These agents will require FDA approval unless steps are taken to modify the approval process. Nevertheless, studies will be needed to demonstrate that the agents are reasonably safe and effective.

As with all systems, those using these agents must be familiar with their proper and inappropriate use. Although the specific pathophysiology of such agents remains to be elucidated, care must be taken to ensure that the casualty so treated is neither over- nor undercoagulated because each has its own associated risks (in other words, too much blood clotting can be as dangerous as too little).

Increased numbers of casualties surviving the immediate battle injury will precipitate an increased need for surgical specialty care. The ability to provide definitive treatment is essential if overall value is to be achieved through this system.

What Are the Potential Challenges Associated with the Development of a Low-Volume Resuscitation Fluid? The extent to which such agents will protect the body during transport in the setting of hypovolemia (abnormal decrease in blood plasma) and the physiologic response and approach to reperfusion (restoration of blood flow to an organ or tissue) require extensive investigation. Although these fluids have the potential to benefit affected tissues (e.g., buffer acidosis and carry oxygen to hypoxic tissues), an extremely small volume may not permit sufficient perfusion to achieve those gains. Testing would require large animal models to assess compatibility.

As with hemostatic agents, the same approval process issues apply, and the use of low-volume resuscitation fluids similarly raises the issue of an increased need for surgical specialty care stemming from increased numbers of casualties surviving the immediate battle injury.

Little is known about the potential for this intervention in humans, although early investigations suggest benefits potentially exist. Further early research into the feasibility of such a system is needed before advanced development can be considered.

What Is the Role of the Combat Life Saver in AAN? The panel identified the Combat Life Saver as an essential component of the response team following battle injury. Although these individuals will not have the primary responsibility for delivering medical care, they must have sufficient training and continuing education to provide needed care in the setting of a widely dispersed battlefield.

Effective Combat Life Saver response will clearly require ongoing training and preparation, yet time for this has not been allocated to these individuals because of the demands of their primary responsibilities. The panel identified this as an essential system—albeit a different sort of system. The other high-priority systems were products or services. This system is basically a training system. With advancements in distance learning, ongoing competence may be achieved through asynchronous learning opportunities either as we know them today or through advances in virtual reality.

RAND Observations and Discussion

The systems that involve transmission of individuals' physiologic information, while potentially valuable medically, warrant prudent discussion. The transmission of patient-specific data must not be misused. Two issues crop up here. First, there must be assurances that the transmission of information will not be intercepted by enemy forces. Even the identification of a transmission has the potential to be detected, and status monitors must be designed to preclude this danger. Second, in the civilian sector, increasing pressures are emerging to protect the confidentiality of patient-specific information with severe fines for practitioners and health care providers for breaching this confidentiality. Just as concerns exist

about FDA approval of drugs and diagnostics, to the extent that DoD is not exempt from this legislation, care should be taken to preserve patient confidentiality.

There may be issues related to the development of monitors and the regulatory requirements for such monitors. To the extent that medical decisions are made based on findings, monitors could likely require FDA approval as a medical device. If the monitor performs laboratory tests (e.g., blood gas measurements, electrolytes, hemoglobin), there may be requirements that the device comply with the Clinical Laboratories Improvement Amendment (CLIA) of 1988.

As with all systems, personnel using the data must be able to interpret findings. While expert systems and algorithms may provide interpretations, those acting on suggestions must have the knowledge to interpret findings and recognize unreasonable recommendations. Continuing competence in the use of the technology is essential.

As with other technologies and conclusions from other panels, issues of approval merit discussion and consideration. The approval process, both by the FDA and perhaps CLIA might be overly burdensome in its current configuration. Technologies addressing the use and interpretation of data, even if "digested" for the end user, require some level of familiarity with the range of findings. Because many of the results may prompt definitive interventions in a short time, users must recognize quickly if instrumentation is offering results consistent with the clinical setting. Studies in the civilian literature continue to suggest that even the simplest-appearing technologies are far from foolproof in clinical practice.

Areas Warranting Further Investigation

Coagulation medicine is an active area within the civilian and military medical communities today. Despite the research and advancements to date, much remains to be learned about the nuances of the coagulation pathways and how they may be selectively activated or deactivated. The potential exists for modulation of the clotting pathways at sites beyond where bleeding control is intended. Consumption of clotting factors and platelets at the site of

injury may predispose patients to increased risks elsewhere, the development of fibrinolysis (i.e., disseminated intravascular coagulation), or undesired hypercoagulation (e.g., intracranial or deep venous thrombosis). These interactions clearly warrant additional research. Efforts to expedite regulatory approval also warrant further exploration in tandem with development efforts.

An additional area that warrants further consideration is the possible extent of casualties related to specific threats. Specifically, the technologies addressed in the panel focus primarily on the intervention and treatment of individual soldiers with direct injury. Some of the scenarios presented suggest that some threats have the potential to result in significant injury to multiple individuals (mass casualty). Systems to support individual intervention may not necessarily have the ability to scale up to intervene and treat large numbers of exposed (e.g., NBC threats) or injured soldiers and civilians.

Chapter Three

MEDICAL TECHNOLOGY PANELS: RESULTS AND ASSESSMENT

This chapter focuses on the RAND analysts' observations about the deliberations of the Medical Technology Panels. RAND analysts observed and reported on the following technology panels:

- Medical Advanced Technologies.
- Military Operational Medicine.
- Infectious Diseases.
- Medical Chemical/Biological Defense.

In each technology panel area observed, this chapter provides, where appropriate, a brief summary of the area examined; a discussion of the promising technologies or functions identified; identification and discussion of the issues; and observations and related discussion, including the identification of areas warranting further investigation.

MEDICAL ADVANCED TECHNOLOGIES

This panel examined the use of advanced information and related medical and other technologies to meet the medical challenges presented in the AAN era. Examples came from the telemedicine and advanced technology programs and included the identification, exploration, and demonstration of key technologies and enabling biomedical principles required to overcome both medically and militarily unique technology barriers. The panel also recognized that enhancements are needed in three broad operational areas to

achieve significant improvement in the support of the future joint warfighter: Joint Medical Readiness, Battlespace Medical Awareness, and Effective Employment of Medical Forces.

Joint Medical Readiness includes the use of distributed medical databases and simulations, dynamic modeling, surgical simulations, and virtual reality to enhance the combat trauma training and medical readiness of physicians, medics, and other health care providers. Battlespace Medical Awareness is concerned with the acquisition, processing, and display of medically relevant information and with providing a common view at different operational levels. Finally, Effective Employment of Medical Forces concerns using information technology to employ medical forces more efficiently. In particular, one goal is to use computer-assisted diagnosis, teleradiology, teleconsultation, presurgical planning and simulation, and minimally invasive therapy to reduce the battlespace medical footprint.

Promising Technologies

The Medical Advanced Technologies panel was unique at this workshop in that a direct correspondence arose between this panel and the Medical Informatics/C4ISR functional panel. As a result, the same technologies developed in the functional panel were considered here, namely:

- Modeling and Simulation,
- Network Management,
- Human-Computer Interface,
- Data Collection and Management, and
- Decision Support Systems.

A brief explanation of each is included in the Medical Informatics/C4ISR Functional Panel section in Chapter Two.

Issues

What Financial and Technical Risks of the Proposed Medical Information Systems Does the Army Medical Community Face? Because

the commercial sector is developing the core information technologies required, it is likely they require very little additional funding by AMEDD. What the panel felt is needed, however, is funding for the integration of the individual COTS components into the particular medical system. Early funding will be required to shape commercial designs toward military need and for military prototype testing. There is also a need for the development of application-specific software for most systems. As a result, the primary financial and technical risks for these systems arise from system integration and software development. However, the necessary investments for these are sufficiently great that perhaps half the systems could be at financial risk.

What Are the Implications of the Joint Standardization Approval **Process?** This process can cause delay and increase cost. However, there was no clear approach proposed that could mitigate this problem, given the entrenched bureaucracies involved. In particular, the various sociological barriers and proprietary obstacles among agencies need to be overcome.

RAND Observations and Discussion

The panel considered the feasibility of the six systems proposed by the Medical Informatics/C4ISR functional panel. All are technically feasible, but current funding does not support any of them. A recommendation was therefore made to establish a medical advanced technology (MAT) research program that integrates all current and future MAT efforts. Such a program would seem to have clear benefits, and we suggest that the panel's recommendation receive further consideration.

The development of a unified information architecture for all medical activities is also a pressing need. This architecture must adapt easily to new technology and be open and secure. It should handle the collection, management, storage, fusion, mining, and transmission of medical data at all echelons of medical care. Given the huge investment already made in this area and the entrenched support for the current systems, it will require strong leadership to market such a proposal to the relevant sponsors.

MILITARY OPERATIONAL MEDICINE

The MOM technology panel explored the investment and execution implications for those scientific and technical programs delineated in the functional panels that were relevant to MOM. The systems considered by the panel were drawn substantially from the Non-battle Injury functional panel; these systems were revised by the MOM panel, with deletions and merges, to produce a related set of systems for evaluation. The systems evaluated by the panel correspond roughly to the top five systems rated by the NBI panel, although strategies to sustain and enhance mental task performance, which had not made the top five systems for NBI, was merged into strategies to sustain and enhance physical task performance. Chapter Two provides a discussion of the systems considered most promising by the NBI panel; this discussion is also relevant here.

Issues

How, in the Anticipated Cyber-Rich Environment with Multiple Inputs, Will Adequate Integration and Interpretation Be Undertaken? Techniques for data reduction and modeling have been emphasized, but for these to provide adequate predictive power, it is necessary that enough "outcomes" are present to permit adaptive systems to undergo accurate learning.

High positive predictive value for potential performance decrements will be particularly important for these systems to be usefully employed by commanders in decisionmaking.

How Will the AMEDD After Next Convert Medical Data to Information? Mechanisms to process data must be an intrinsic part of systems in which data sensing is performed with the goal of transmitting useful information. (This includes most or all of the systems considered here.)

How Can the Potentially Controversial Nature of Pharmacological Performance Enhancing/Sustaining Interventions and Genetic Screening Be Managed? The manner in which these interventions are presented and the degree of evidence regarding benefit and risk will be essential to obtain acceptance of these measures.

The panel felt that potential benefits to the soldier, to the mission, and to the nation should be analyzed and emphasized. Risks should also be carefully considered—zeal to enhance performance in one domain should not cloud consideration of possible adverse consequences in other domains. Long-term as well as short-term consequences should be considered (for instance, will mandated use of a controversial intervention meaningfully reduce enrollment of highquality personnel in careers in the armed forces?).

RAND Observations and Discussion

With regard to injury modeling, the term "modeling" provoked some dissent within the group. Several panelists were concerned that complex physiological modeling with multiple interacting factors and parameters, particularly efforts geared toward grandiose integrated models of the whole body, were unlikely even by 2025 to yield useful information. The number of potentially relevant parameters is enormous (particularly in light of individual differences in relative muscle size, muscle insertion areas, ligament integrity, and many asyet-undefined factors associated with muscle function), and predictive modeling efforts of biological phenomena involving many interacting parameters have historically been time- and money-sinks, often with no useful end-product. The panel agreed, however, that ongoing efforts should be made on a less-grandiose scale to evaluate responses to forces in real or contrived settings, incorporating and taking measurements from cadavers (as is currently done) and simulation dummies, with biomechanical impact consideration integrated into design efforts to minimize physical injury; to provide sensor information to feed into the warfighter status monitor; and to individualize (where relevant) design of new devices to reduce performance decrement and injury. This was considered to represent technology investment areas 6.1 and 6.2.

Investment in methods for adaptive integration of complex data, in a system with properties of fault tolerance and graceful degradation, will benefit the AAN. Physiological data will be beneficial to identify likely candidates for inputs. We suggest that the ability to convert data to information will not necessarily rely on accurate physiological models. For example, in cardiovascular risk prediction, the best funded and arguably most complete field of risk prediction in

52

medicine, a variety of predictors (demographic, biochemical, genetic, psychological, extrinsic) have been identified and their predictive role and interactions have been statistically identified, even when we do not necessarily have the correct physiological model for the role of that input (and even when the physiological model is later found to be wrong or incomplete). More important than accurate physiological models will be generation of useful "outcome" data to train adaptive systems on the relation between inputs and outcomes.

INFECTIOUS DISEASES

The Infectious Diseases Technology Panel focused on the prevention, diagnosis, and treatment of endemic and emerging infectious diseases with the potential capability to seriously diminish military operational readiness. The panel considered the recommendations of multiple functional panels; however, primary input came from the deliberations of the Disease Functional Panel. At the Disease Functional Panel, discussions distilled multiple systems into a specific set of systems for further discussion. The panel considered the composite systems by first assessing the contributing systems and then assessing their overall feasibility.

Promising Technologies and Functions

• Urban, Jungle, and Desert Soldiers Systems. These systems include common diagnostic systems and specific suites of vaccinations¹ and drugs.² The panel acknowledged the likelihood that future engagements will occur in all of these areas. Military operations will be threatened by different infectious diseases in these settings, particularly with respect to infections and vectors and climatic conditions specific to the area of deployment. The overall effort is directed at providing a system of vaccines, drugs,

¹Urban: HIV, dengue fever, diarrhea, malaria, hantavirus, scrub typhus, wound vaccination, Rapid Manufacture Vaccine (RAMVIT), Deployment Area-Specific Multicomponent Immunization System (DAMIS). Jungle: dengue, malaria, scrub typhus, wound vaccination, RAMVIT, DAMIS. Desert: RAMVIT, DAMIS, wound vaccination.

²Urban: malaria, antiviral. Jungle: malaria, antiviral, leishmaniasis, lethal virus countermeasures (high-risk containment agents and emerging pathogens, including hemorrhagic fever viruses). Desert: antiviral, leishmaniasis.

diagnostics, and vector control, as appropriate, to prevent these diseases. Some efforts here are partially funded and, although the panel concluded there was moderate risk involved in achieving this composite systems (and many of the components), the payoff in terms of reduced morbidity was well acknowledged.

- Mobilization System. This system includes antiviral drugs and diarrhea, wounds, and Group B meningococcal vaccines. The focus of this system acknowledges that when U.S. forces are mobilized, they generally occupy crowded spaces. Many recruits are in close proximity to each other. This setting facilitates transmission of diseases from individual to individual primarily, although not exclusively, through respiratory means. Research is currently ongoing with respect to Group B meningococcal infection and for some adenovirus types that have historically been problematic with respect to causing morbidity among recruits and others who live in close proximity.
- Unique Environments System. This system includes a common diagnostic system, antiviral drugs, and diarrhea, malaria, hantavirus and wound vaccines. This composite system acknowledges that soldiers are often situated in unique environments, such as contained environments where they are in close proximity to others who may harbor diseases. Transmission can occur through common routes (e.g., fecal-oral, respiratory), and research here is focused on development of a system of vaccines, drugs, and diagnostics that will diagnose, prevent, and treat these diseases. Norwalk agent was specifically acknowledged as a common source for disability.
- Common Diagnostic System. This system acknowledges that the ability to diagnose many infectious diseases that threaten military readiness and operational effectiveness is for the most part confined to specialized laboratories with expertise in diagnosing infectious agents. Some of this effort is commercially funded, and some is governmentally funded (e.g., CDC). The ability to identify endemic threats in anticipation of or during military deployment is important to prevent morbidity associated with unexpected outbreaks. The system proposes a portable rapid and accurate diagnostic system for use in forward hospitals followed by development of a more portable, handheld type of unit.

Funding for this system already exists in part, and expenses would be expected to be shared by the Biological Defense efforts. This is a highly complex task; that is why the panel believed that the risk was moderate, although with appropriate efforts that risk could be lowered. The system will require a validated pathogen database with sufficient data to be able to interpret diagnostic findings correctly.

- Lethal Virus Countermeasures. This system acknowledges the lethal threat posed by many viruses, particularly members of the hantavirus family. Although the initial focus of discussion centered on hantavirus infection, the conclusion was that countermeasures should be developed to address all classes of lethal virus infections. This refined system is included in the discussions above.
- DAMIS. There were three components to this composite system: adjuvants, delivery systems, and active and passive protection. Overall, this system proposes the development of polycomponent vaccine packaging and delivery systems to provide immunity against deployment area-specific diseases and BW threats. The adjuvant component assists the active and passive protection component in developing a protective immune response. The delivery system provides the "packaging" of the other subcomponents of the system to assure the desired response. Discussion arose about the development of a single "shot" to mitigate the problems associated with multiple vaccines with multiple time intervals. However, suggestions were put forth during the panel meetings that intermediary solutions would partially accomplish the desired outcomes. Inherent in the desired outcomes of this system is a shortening of the induction period, perhaps achieved through better antigen presentation. The panel for this system recommended that DoD develop a production center or system that includes the production, storage, and tracking of vaccines. The panel concluded that although the commercial sector would be interested in developing similar systems, the DoD requirements, in terms of the anticipated threats, would be quite different. The panel believed this to be an important system for further development.

Issues

How Much Interest Will the Commercial Sector Have in Developing the Technologies Proposed? DoD has a unique leadership role in the development of diagnostics and treatments for infectious disease. The panel felt DoD's efforts should be leveraged with commercial and governmental partners to achieve the most success. In many areas, these efforts are already under way. While partnership is important, outsourcing of all current DoD research efforts is improbable. As revolutionary technologies are developed, opportunities to apply them to other purposes will arise. Some technologies developed in the private or academic centers may apply to military operations. For example, once a platform (e.g., polymerase chain reaction) is known, strategies may be developed to assist in military operations (e.g., unique biological threats in areas of deployment).

How Ready Will DoD Be to Respond to Different Infectious Disease Threats? With respect to infectious diseases, a complex, dynamic threat profile exists. DoD should be cognizant of this as future investments are considered. Timelines with respect to assessment, diagnosis, and treatment will need to be compressed. Normal development times are often much too long to be effective. Concern was expressed that the experts currently working in these areas of infectious disease are aging. Many will be approaching retirement, and it will be important, in the immediate period, to recruit new scientists in time to maintain the gains that have been achieved.

How Quickly Will DoD Be Able to Respond to Regulatory and Oversight Considerations? The need for testing capabilities to meet regulatory requirements remains. The FDA's standard requirements established for safety and efficacy may preclude timely development of important diagnostic and therapeutic tools.

RAND Observations and Discussion

The Infectious Diseases technology panel believed all the systems proposed by the Disease functional panel to be within reach. However, the majority of the technology panel came from the major contributing functional panel. The feasibility of the proposed systems warrants further discussion with others less directly involved in synthesizing the initial systems. Although many of the systems may be technically feasible, the likelihood of achieving those systems within the next 25 years could increase through further deliberations, including specific plans for operationalization of these system plans.

The panel concluded that DoD, Medical Research and Materiel Command (MRMC), and the Defense Advanced Research Projects Agency (DARPA) are essential in helping the United States respond to current and emerging biological warfare and infectious disease threats. Although the commercial sector will have interest in some of the technologies, the specific threats to the military are different, requiring specific investment by DoD. It is important that DoD maintain its core capabilities and competencies in the area of infectious disease diagnosis and treatment, particularly as it relates to threats that would not be encountered by the civilian sector.

Areas Warranting Further Investigation

DoD needs to maintain an active presence in research, science, and technology related to infectious diseases. Many issues in this area essential for military operations are not of interest to the commercial sector because of a poor return on investment. Such an approach requires, in essence, generalist microbiology scientists. Academia encourages in-depth expertise in narrow areas, while military research encourages broad-based expertise in infectious diseases. The military, therefore, is much better equipped to respond to new and emerging threats (in conjunction with the CDC). Consequently, DoD would benefit from investing in the next generation of military scientists in this field.

Molecular diagnostics should be emphasized as a source for rapid detection of infectious agents. This technology has proved valuable in many areas of laboratory medicine, and it is well suited, with further investment, to achieve many of the goals set out by the Infectious Diseases panel. This effort is easily combined with activities in the academic, commercial, and other governmental sectors.

MEDICAL CHEMICAL/BIOLOGICAL DEFENSE

This panel examined technologies to preserve combat effectiveness by detecting biological and chemical threats, providing prophylaxes for these threat agents, and supporting medical management of chemical/biological agent casualties.

Promising Technologies and Functions

The panel discussed nine technologies in depth; these fell into three categories: prebattle treatment (e.g., vaccines), detection and diagnosis, and treatment. However, the treatment technologies were added as an issue by the panel and were not discussed in detail as a system card or cards. A theme underlying the discussion of promising technologies was that a fielding date of 2025 was not looking too far into the future in terms of vaccines or other medicines that would require FDA approval, because of the length of the approval process. In short, technologies to be fielded by that date should already be in at least 6.1 or 6.2 development. For this reason and because panel members well understood the biological limits of technology, this panel generally took a more grounded approach to future technology by examining how current technologies could be capitalized on instead of conceptualizing completely new strategies.

Issues

What Regulatory Challenges Does AMEDD After Next Face in Fielding BW and CW Countermeasures? The panel consensus, arrived at quite early, was that a 10-year approval cycle should be used as a planning factor in proposing new technologies requiring FDA approval. The current approval process makes highly effective R&D difficult. For example, if a biological agent threat is engineered and therefore requires new vaccine development, the approval time must be considered as a planning factor. Further, the approval process is unique for these technologies, because in some cases no disease state exists (e.g., smallpox). Therefore, any side effects of testing in humans may be unacceptable. Appropriate and approved surrogate animal models were identified as a significant need.

It was suggested to the panel that it characterize an approval process that would be more streamlined and better meet the needs of DoD, including some type of realistic risk assessment process that adequately considers the threat. This would enable the panel to provide its estimation of the feasibility of technological development within

the AAN time frame in light of the current and envisioned approval process. The panel, in effect, decided not to forward the approval process as a policy issue. An observation can be made here that other government agencies (Department of Energy (DOE) National Laboratories, the Department of Health and Human Services (HHS), CDC) face a similar policy hurdle, and perhaps these agencies should engage DoD in an informed debate about the risks and benefits associated with developing chemical and biological defense countermeasures within the current FDA approval framework.

What Role Does Aversion to Vaccine/Prebattle Medications Interactions Play in Chemical and Biological Defense R&D Efforts? Panel members involved in vaccine research (and the approvals process) stated that the DoD position on interactions is more conservative than that of the FDA. In short, the FDA does not require safety studies concerning interactions unless the medications are administered at the same time in the same manner and formulation. Panel members assumed that DoD's position is to consider potential interactions of all preventive medications. The implications of this position are considered further in the observations section below.

Should DoD Perform Chemical and Biological Defense R&D Alone? Various members of the panel said that other U.S. agencies and allies have undertaken major efforts in this area. For example, one member stated that DOE was investing 15 full-time equivalent employees for chemical agent detection as part of a \$100 million domestic preparedness budget. The UK plans to field a plague vaccine in 2003. This technology exists in AMEDD After Next as a system card.

AMEDD may benefit from increased communication with organizations pursuing similar R&D efforts. If this communication is already occurring at a level not represented by the panel members, then the scientists conducting the research should be more involved.

What Is the AMEDD Responsibility to Develop Chemical and Biological Defense Technologies to Support the Homeland Security Mission? This mission was unclear to the panel. A related discussion concerned an orthopox virus currently in human trials. This virus will be submitted for regulatory approval for use in healthy adults—e.g., nonimmunosuppressed, nonpediatric, nongeriatric individuals. In short, the approval will be for use in typical soldiers. When the

issue of whether this limited approval will affect the homeland security mission was raised, it received little attention. The tacit assumption seemed to be that this mission responsibility belongs elsewhere or is at best ill defined in the AMEDD.

RAND Observations and Discussion

The focus of the MTW-99, across several panels, fell on prebattle medications, including vaccines, chemical agent defense medications, hemostatic agents, etc. As mentioned previously, the panel assumed that DoD considers all potential interactions of preventive medications. One panel member observed that 25 different new medications could be easily conceivable by 2025. Testing possible combinations of 25 different medications for interactive effects results in more than 30 million combinations (225)! It is unclear whether this is indeed DoD's policy, but the panel perceives that it is. The testing of all possible combinations is clearly not feasible, however, and environmental exposures complicate the process further by creating more possibilities for interaction. Is the perception of a highly risk-averse policy an outcome of the currently deliberated illnesses that affect Gulf War veterans, in which interactive effects might have played a role? Regardless, DoD should consider the feasibility of any comprehensive prebattle medication safety policy. At the extremes are policies of assumed consent versus a daunting testing effort, which seems unlikely to be successful scientifically or financially. Other options to consider include the following:

- Modeling interactive effects through techniques similar to the Qualitative/Quantitative Structure Action Relationships system or other means, to provide more direction for safety testing.
- Conducting informed risk assessments to balance the risks and benefits of prebattle versus therapeutic care strategies, including the use of broad-spectrum therapeutics (e.g., antivirals) or other prophylactic technologies (e.g., immunomodulation techniques) versus specific vaccines.
- Pursuing more research into multivalent vaccines to protect against suites of threats (see discussion below on multi-versus omnivalence), thereby limiting the number of individual medications to be tested for interactions.

Most important, the chemical and biological threat is evolving. The best defense for this threat is continuous development and advances in basic research, including immunobiology, molecular biology, and selection of appropriate surrogate animal models. If one considers each genetically engineered biological agent as an emerging disease (which, in effect, each is), the value of a basic scientific ability to keep up with this pace of emerging diseases is high. To this end, we suggest that AMEDD continue to invest in 6.1 and 6.2 biological research and explore ways to recruit and retain highly qualified scientists.

We also recommend that the AMEDD explore broadening its communications with other U.S. government agencies involved in chemical and biological defense research to leverage these sources where feasible and to initiate risk-based discussions among these agencies, DoD, and FDA regarding the registration process for chemical and biological defense technologies.

Areas Warranting Further Investigation

Multivalent Vaccines. While this was not strictly an omission, the panel was hampered in its discussion of vaccine technology because the system cards considered in this area included requirements for protection against genetically engineered strains of BW agents as well as a prophylaxis against *all* threats. This protection would require development of an omnivalent vaccine. A more promising approach may be to consider development of several multivalent vaccines—that is, single vaccine "cocktails" that protect against suites of agents (such as viral families).

BW Agent Pharmacologics. The panel recognized the need for post-exposure medical technologies in chemical and biological defense. For example, antiviral medications should be further researched for several reasons. Not all vaccines are 100 percent effective, and, in some cases, specific vaccines may not be given for several possible reasons (logistics, lack of medical intelligence, etc.). Furthermore, these types of therapeutic strategies may also benefit the homeland security mission. As other agencies (e.g., CDC) may also be working in this area (specifically for homeland security), AMEDD may consider collaborative efforts in this area.

IMPROVING THE WORKSHOPS

In general, this workshop was well designed and executed. Participants were knowledgeable in their fields, they were generally provided a forum to express their ideas, and the extreme time pressures associated with most games, seminars, and workshops of this kind were generally absent. The result was the identification of a rather comprehensive set of medical and medical support technologies needed to support AAN-era military operations.

That said, some aspects of the workshop could be improved. This chapter lays out a conceptual framework for how the workshops should feed into the process for developing medical systems. It then discusses the structural attributes of a good workshop and turns to a detailed discussion of how one key input—future operational capabilities—is derived. The chapter concludes with a description of a needed postworkshop event.

CONCEPT FOR MEDICAL TECHNOLOGY WORKSHOPS

A good workshop synthesizes. The game inputs are the desired capabilities from the operational medical community on the one hand and the technologies (not formally articulated) from the participating medical doctors and scientists on the other. The outputs are military medical and medical support systems. Figure 4.1 depicts the process. In it, the workshop synthesizes the desired capabilities with the relevant technologies to yield candidate systems. The seminar participants are a significant part of the input mix. The military medical personnel must be capable of articulating the desired medi-



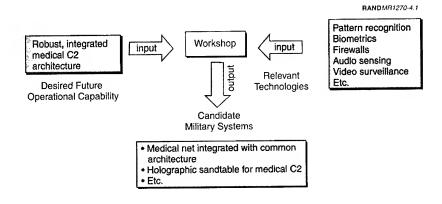


Figure 4.1—Medical Systems as Syntheses

cal support capabilities and the medical doctors and scientists must be chosen for their expertise in the requisite technologies.

TECHNOLOGY WORKSHOP STRUCTURE

The medical technology workshop is essentially a brainstorming session. For brainstorming sessions to be productive, workshop planners must produce an environment that encourages the free flow of ideas. This means no preconceived notions of the "correct" medical solution and no technological "pet rocks." A structure that is likely to prove successful has the following attributes:

- Small: The participants at any one group should number five to 10. Large groups tend to produce one or two individuals who monopolize much of the meeting time and tend to intimidate less-forceful participants.
- Short: Meetings should be scheduled for one morning only. It is
 difficult to remain creative, innovative, and focused for much
 longer than that. Experience with the RAND Day After Games¹
 has shown that a morning of intense activity is about optimal.

 $^{^1}$ The Day After series of games focuses on policy issues by developing a crisis scenario set in the future but absent an articulated policy. The game participants must suggest

Focused: Each session should focus on two or three related capabilities. This allows seminar planners to group technologists by field of expertise.

In addition to the structural suggestions above, two other aspects of the workshops might benefit from a change. The use of system cards has the tendency to focus the participants more on process (getting through the cards) than on substance. In addition, few of the participants felt adequately qualified to assess the relative impact of increases or decreases in funding for research in the technologies identified as critical.² The former suggests a more direct link between required future capabilities and technologies, and the latter suggests altering the process to include participants with programming experience.

DERIVING FUTURE OPERATIONAL CAPABILITIES

The starting point for developing an appropriate list of FOCs is those missions that AMEDD personnel will have to perform in the future. These missions derive from the operating procedures specified for the AAN Battle Forces and the AAN Hybrid Forces and are set forth in the document, Franchise Considerations: Concept for Medical Health Support 2025, supplied to the workshop participants. The document articulates a medical support plan for the AAN Air Mobile Battle Force. The medical missions described in the document suggest operational capabilities, some of which were included in the 13 FOCs discussed at the workshop. This and other documents dealing with the other Battle Forces³ and with the total Hybrid Force are essential inputs to the process of generating capabilities.

short-term policies to avert the crisis. Their efforts fail, the crisis occurs, and they are then asked to resolve it. After these two steps, the participants are brought back to the present and are asked to suggest policies that might avert the crisis. See Mussington, Wilson, and Molander (1998) for an example of this methodology.

²Ironically, although the panel leader for the Medical Advanced Technologies Panel was, in fact, the Director of Acquisition and Advanced Development at U.S. Army Medical Research and Materiel Command, Fort Detrick, his panel chose to ignore the requirement to assess the impact on programs of increases and decreases in funding levels.

³Combat health support to the Air Mobile Battle Force was considered an "archetype" of combat health support to the other Battle Forces. The major impact on medical

64

From examining the 13 FOCs included in the game material, it is possible to infer future missions. However, it is also possible to conclude that the "future" capabilities are designed to support existing medical support requirements. Not that this is bad. It is entirely possible for a future requirement to be an existing one. However, it is important that the required future medical support missions drive the capabilities-generation process.

Table 4.1 is an example of how an AAN Battle Force Mission generates future medical support missions. The list is far from comprehensive and, clearly, the medical missions will overlap. The characteristics of the AAN force having the greatest implications for medical support are rapid deployment, high-tempo operations, a large area of operations, and small, widely dispersed units.

Table 4.1

Deriving Medical Support Missions from AAN Missions

AAN Air Mobile Battle Force Missions (partial list)	Implied Medical Support Missions (partial list)	
Deploy from fort to combat in 72 hours.	Provide medical support prior to and during deployment. Rapidly deploy medical support units and facilities.	
Operate in permissive and nonpermissive environments.	Train combat soldiers in self and buddy aid. Include Future Combat Medic (FCM) in Battle Force organization.	
Execute continuous high- tempo combat operations.	Provide medical care for wounded soldiers at the unit level.	
Operate over an area up to 72,000 square kilometers.	Locate and rapidly evacuate WIA from widely dispersed area of operations.	
Self-sustained for 48–72 hours.	Ensure that deployed units possess basic resuscitation equipment. Continuously monitor each soldier's health status	

support of this and other AAN-era forces derives from its widely dispersed area of operations and increased combat tempo.

The next step in the process is to analyze the medical support missions to identify the required capabilities. The FOCs provided to the workshop participants are examples of how capabilities should be written. It is important that the capabilities statement not suggest systems to achieve them. For example, the mission to "Provide medical care for the wounded soldier at the unit level" in Table 4.1 suggests FOC 005: Far-Forward Surgical Support:

Provide forward deployed emergency resuscitative surgery across the range of military operations, to include NBC environments. [The required] capability to project surgery forward increases as a result of the extended battlefield. [Implied capabilities include:]

- To provide urgent resuscitative surgery for casualties who require surgical stabilization before [further] evacuation.
- To provide improved shelter systems that allow for both tactical and strategic deployability, quick setup, and a rapid-response surgical capability under environmentally controlled conditions.

Note that the phrasing does not suggest medical or other systems to achieve the required capabilities. It is important to abide by this rule. Otherwise the workshop might get mired in a debate on the merits of the proposed system.

Table 4.2 lists the capabilities suggested by the missions in Table 4.1. The list is not exhaustive and is meant to be only illustrative. Note that the capabilities are stated in terms of attributes required of the medical support force to accomplish the mission. There is no reference to specific medical or medical support systems that might achieve these capabilities. It is also possible that several capabilities are required to accomplish a single mission and, conversely, the same capability may serve, in whole or in part, to accomplish several missions. Finally, where possible, we link the capability to the FOCs.

It is important to remember that a capability is not the same as a system. By including systems in such a list, some technologies or alternatives may be forestalled. In some cases, the military operators may consciously select a technological or systems option. For

Table 4.2 **Deriving FOCs from Future Medical Missions**

Medical Mission	Requirement	FOC
Provide medical support before and during deployment.	Improve air/land transport for medical systems Expansion of onboard treatment space Accessible onboard storage of medical equipment	013, 007
	Improve soldier sustainability through prevention of diseases, radiation injury, other combat hazards, and stress	
Rapidly deploy medical support units and facilities.	36 to 72 hour deployment capability Modular medical laboratories that sup- port split-based operations	013, 010
Train combat soldiers in self and buddy aid.	Improve training programs for primary care givers and combat soldiers	
Include FCM in Battle Force organization.	Provide medic with capability to function under all combat conditions Provide resuscitative surgery across a range of military operations	005
Provide medical care for wounded soldiers at the unit level.	Provide resuscitative surgery to casual- ties in need of stabilization before further evacuation Develop improved shelter systems	005
Locate and rapidly evacuate WIA from widely dispersed area of operations.	Provide seamless air/ground evacuation system Communicate with supporting and supported units en route Maintain situational awareness Provide improved en-route medical care	001, 002
Ensure that deployed units possess basic resuscitation equipment.	and monitoring Develop systems to project surgery forward Ensure survivability of FCM Provide primary care givers access to medical personnel	005, 003
Continuously monitor each soldier's health status.	Design digitized patient health record systems Develop patient accountability systems	002, 003, 006

example, after each FOC in the Workshop Guide, several "observations" were recorded by members of the panel that met to formulate these objectives. In several cases, these observations are

strong hints at systems that might achieve some or all of the capabilities described. One example is the observation that a patient transport pod might support FOC 005: "Far-Forward Surgical Support." The problem is that a suggestion that an evacuation pod might satisfy the need to evacuate casualties from far-forward areas may preclude a productive discussion of alternative evacuation methods or perhaps alternatives to evacuation.

FORCE INTEGRATION

The technology workshops identify candidate military systems, but the task is not done because it remains to be seen how they fit into the force. Force integration seminars take the next step. Building on the medical technology workshops, force integration seminars address how the medical systems and medical support systems might be integrated within the future Hybrid Force. In some cases, medical systems can function only when combat units are fully deployed. Such is the case with the FCM. In other cases, the medical system is relatively independent of the combat forces. For example, a rear-area medical hospital might qualify in the latter category. In either event, some form of integrating event needs to be conducted to examine how and where the future medical systems fit in the overall AAN-era Hybrid Force.

Participants at integration seminars should include Army operators familiar with Army doctrine and combat systems and military medical operational personnel. Given that the medical systems and medical support systems generated in the medical technology workshop are essentially military end-items with an operational concept for their use, the logical next step is to integrate them with operational concepts for future forces.

Inputs to the seminars are the medical systems, the future force structures, and their operational concepts. Outputs consist of integrated operational concepts for medical support to future combat operations. Figure 4.2 illustrates the process.

This essentially completes the analytic circle. The process started with the medical missions implied by the AAN missions. This step now examines how the medical systems identified in the workshop support the AAN-era Hybrid Force.

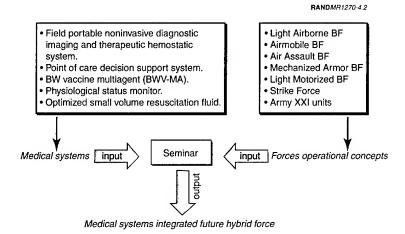


Figure 4.2—Force Integration Seminar

CONCLUSIONS

This workshop was a useful exercise and yielded significant insights about future medical operational capabilities and technologies. The process also revealed several emerging areas of concern that warrant further analysis:

The relationship between AAN concepts and the medical concepts to support them seems somewhat disconnected. At the heart of the issue is the AAN Battle Force that conducts hightempo, dispersed operations and is inherently lethal, mobile, and survivable, although Army XXI and other legacy forces will be in the force structure during the AAN era. The AMEDD has designed a concept to address the medical needs of the Battle Force that is highly reliant on the evacuation of a manageable numbers of casualties and the leveraging of cutting edge technologies—particularly in the area of patient stabilization—to deal with the dispersed nature of the future battlefield and desire to have a small in-theater medical footprint. Where the AMEDD concept becomes risky is when casualties—friendly, coalition, enemy, and civilian—reach moderate to high levels. As part of the first day's presentations at MTW-99, a medical concept for supporting a Battle Force in action was briefed. Strong concerns were voiced about providing timely care to severely wounded soldiers, getting other than buddy aid to their location, and the long evacuation distances (and times) associated with widely dispersed Battle Force operations. Indeed, a number of participants in the workshop expressed doubts throughout the course of the workshop about the ability to medically support Battle

- The asymmetric threats facing deployed forces and forces in CONUS preparing to deploy are serious concerns in the AAN era.
 Weapons of mass destruction (NBC weapons) have the clear potential to create mass casualties that the AMEDD and other agencies must address.
- Much of the future operational capability of the AMEDD is tied to the promise of new or improved technologies being developed and fielded in sufficient quantities to address the medical needs of the force. Some of these are largely military-unique systems, e.g., the medical evacuation pod, and critical to the support of AAN-era forces. What was largely absent from the discussions at the MTW-99 was an assessment of hedging strategies to deal with the eventuality that critical technologies and systems might not be available in the future.

A theme that resonated throughout the workshop was the aging of the AMEDD researchers and the difficulty of attracting promising young researchers. This condition is important, because many of the research areas this community deals with are of little interest to commercial laboratories but are critical to military operations. Concern was voiced throughout the workshop that this in-service capability is disappearing, with potentially dire implications.

Appendix

AMEDD AFTER NEXT TECHNOLOGY WORKSHOP-99— PANEL OBJECTIVES

MEDICAL INFORMATICS/C4I (FUNCTIONAL) PANEL

This panel focused on the utilization of advanced communications, electronics, computers, and software and information technologies to meet the challenges presented in the AAN era. Areas the panel was charged with considering included the following:

- Integration of health threat information into medical and nonmedical mission planning tools.
- Asset visibility and management within the battlespace (supplies, medical units, casualty flow).
- Distribution and archiving of individual and unit exposures to health threats presented by enemy weapons and the environment.
- Training of individuals and units in the use of basic and advanced medical techniques in the AAN field environment.
- Enhancing direct medical care with smaller deployed medical infrastructure able to operate under austere operational conditions.
- Collection, distribution, and archiving of individual medical records.

COMBAT SERVICE SUPPORT (CSS)/EVACUATION/ **HOSPITALIZATION (FUNCTIONAL) PANEL**

This panel had a broad charter to examine enhancements to all areas of health services, including medical, surgical, laboratory, and preventive medicine capabilities. Specifically, the panel was focused on the capabilities required by medical units, from the most forward deployed surgical detachments or aid stations, through the echelons of care to CONUS fixed facilities. It was also charged to give special attention to identifying approaches that would reduce the footprint and sustainment requirements of deployed units. Within the division area, the panel examined facility and evacuation infrastructure requirements, although it was understood that some overlap would occur with the Battle Injury panel in considering medical treatment requirements at the level of the most forward deployed medical unit.

The panel was also tasked to identify modifications to equipment sets, shelters, and other medical and nonmedical capabilities from the baseline configuration of deployable units proposed in the Medical Reengineering Initiative, that would enable tailoring of the Medical Reengineering Initiative force to meet the specific challenges of providing medical support to AAN-era Strike/Battle Forces. The initial panel objective was to identify those systems required to implement the "Concept for Medical Health Support 2025," described in the preworkshop reading materials. Furthermore, the panel was asked to consider medical evacuation platforms specifically, including any special requirements for care on the move.

DISEASE (FUNCTIONAL) PANEL

This group focused on countering threats from disease-causing organisms, regardless of origin, whether endemic or spread by enemy action. The panel was tasked to initially focus on exploring the implications that warfighting in the AAN era might have on the relative priority of disease threats. The panel was also asked to address approaches that would reduce the time necessary to induce adequate levels of immunity, reduce side effects, and generally increase the availability and readiness of healthy warfighters. Excluded from consideration by the panel were systems and solutions that would be carried by individual soldiers or unit medics in the form of antidotes to weaponized threats. Further qualifications were to consider treatment regimens that would minimize effects that could impair military performance and should minimize the period of nonavailability for duty. Finally, the panel was to consider approaches that would reduce development time, including that required to secure FDA approvals and reduce manufacturing, procurement, and sustainment costs.

NONBATTLE INJURY (FUNCTIONAL) PANEL

This panel focused on the identification of methods to enhance warfighter health and performance in the face of occupational or environmental health threats, initially looking at those threats that would be created or magnified by military operations in the AAN era. The panel was asked to examine methods to increase physical and mental stamina and performance and reduce occupational injury and to consider solutions to the acute and chronic health risks imposed by environmental threats (heat, cold, or levels of toxic environmental pollutants), including monitoring of individual health and performance (e.g., Warfighter Physiological Status Monitoring efforts) and algorithms to predict, assess, or modify individual health and performance. In its deliberations of the occupational health and performance challenges of the AAN era, the panel was also asked to examine countermeasures to the risks imposed by U.S. use of AANera warfighting systems. Additionally, the panel was charged with identifying the required investments in biomedical contributions to the design of nonmedical AAN systems to ensure that health or human performance factors related to system operation neither degrade the performance of the warfighting system nor increase acute or chronic medical problems for the operators.

BATTLE INJURY (FUNCTIONAL) PANEL

The focus of this panel was on increasing survivability and reducing morbidity in casualties in the AAN era by equipping individuals, "buddies," and other first responders with enhanced capabilities to reduce the KIA rate. Included was the identification of treatment capabilities that would extend the "golden hour" so that the DOW rate does not increase despite delays in evacuation expected under many AAN operational scenarios. The panel was asked to explore

diagnostic devices and sensors that the Warrior Medic would bring to the casualty, supplementing health status information derived from the sensors worn by the casualty. The panel was also charged with addressing the capability requirements from the point of injury through the most-forward surgical detachment.

MEDICAL ADVANCED TECHNOLOGY (TECHNOLOGY) PANEL

This panel focused on the utilization of advanced information and related medical and nonmedical technologies to meet the medical challenges presented in the AAN era. The panel was asked to incorporate dominant battlespace awareness and full-dimensional protection into its discussions of leveraging information to accomplish the primary military medical mission of providing and maintaining readiness and of providing medical services and support to the armed forces during military operations. The panel was asked to look for examples in telemedicine and advanced technology programs, including the identification, exploration, and demonstration of key technologies and enabling biomedical principles required to overcome technological barriers that are both medically and militarily unique. It was acknowledged in the panel's instructions that both medical and nonmedical investment in the pertinent enabling technologies might be required and identification of opportunities for leveraging efforts among medical and nonmedical materiel developers and among government and nongovernmental organizations would be encouraged. Additionally, the panel was told that enhancements were needed in three broad operational areas to significantly improve support to the future joint warfighter:

- Joint Medical Readiness. The use of distributed databases and simulations, dynamic modeling, surgical simulations, and haptic feedback-supported virtual reality to enhance the combat trauma training of physicians, medics, or other health care providers, medical teams, and units; enable collaborative mission rehearsal; and improve the medical readiness of all personnel assigned to the joint warfighting force prior to deployment.
- Battlespace Medical Awareness. Medical situational awareness and display systems to rapidly acquire medically relevant infor-

mation, precisely process and direct multimedia medical data to the appropriate user, and maintain the integrity of the processed information to provide a common medical view of the battlespace at different echelons and operational levels.

Effective Employment of Medical Forces. The capabilities to more effectively and efficiently employ medical forces within the battlespace. Capabilities in this area allow commanders to dynamically integrate tactical and supporting medical assets throughout the theater and the CONUS supporting base to better coordinate health care delivery using ongoing assessment of the battlespace to optimize the application of multiechelon medical forces and assets. At the individual health care provider level, capabilities for computer-assisted diagnosis, teleradiology, teleconsultation, presurgical planning and simulation, and minimally invasive therapy provide enhanced care while shrinking the medical footprint.

MILITARY OPERATIONAL MEDICINE (TECHNOLOGY) PANEL

This panel examined the protection of health and sustainment of military performance in the face of stresses that confront soldiers in a deployment. The panel looked specifically at research directed to an understanding of the physiology of the deployed soldier, the development of improved damage risk criteria to protect against materiel and environmental hazards, and the development of specifications, algorithms, and models for strategies and interventions to protect health and performance. Areas of emphasis included the following:

- Environmental physiology and metabolic interventions such as thermal physiology and injury prevention, nonfreezing cold injury protection, sustainment in mountainous terrain, metabolic regulators to optimize performance in adverse environments, nutritional optimization of soldier mental status, optimization of physical performance, and musculoskeletal injury prevention.
- Biodynamics and injury sciences research, such as blunt trauma models, soldier performance and injury-based criteria and crash injury protection, and laser eye injury protection and treatment.

 Neurobehavior and toxicology research, such as deployment exposure assessment systems for environmental contaminants, rapid assessment methods for drinking water safety, combined toxic gas models, and military health behavior promotion and interventions.

INFECTIOUS DISEASES (TECHNOLOGY) PANEL

This panel was focused on the prevention, diagnosis, and treatment of endemic and emerging infectious diseases with the potential capability to seriously diminish military operational readiness. Diseases of principal interest were malaria, infectious bacterial diarrhea, and dengue fever. The ongoing R&D efforts reviewed included therapeutic measures for infectious diseases, including studies to synthesize, screen, and develop therapeutic drugs for malaria, leishmaniasis, and other militarily relevant infectious agents. R&D efforts examined for preventive measures for infectious diseases included vaccines, antiparasitic drugs, structure-based drug design for novel antimalarial drugs, epidemiology, diagnosis, and vector control.

COMBAT CASUALTY CARE (TECHNOLOGY) PANEL

This panel focused on research programs that provide integrated capabilities for far-forward medical care that would reduce the mortality and morbidity associated with major battlefield wounds and injuries. The goals of the R&D efforts in this area are to extend the "golden hour" for treatment to improve survival and minimize morbidity after life-threatening injuries and to provide military medical capabilities for far-forward medical or surgical care of battle and nonbattle injuries. A primary emphasis is the identification and development of medical techniques and materiel for early intervention in life-threatening battle injuries. These efforts are directed toward principles and technologies available to render self aid and buddy aid; enhancements in techniques, methods, or materials for basic and advanced life support for severely injured persons; management, sustainment, and monitoring of severely injured casualties during episodes of delayed or protracted evacuation; management of patients when treatment is delayed as a result of temporary overloading of battlefield facilities; and enhanced management of triage of large numbers of patients and comprehensive and staged treatment at field hospitals. The following combat casualty care science and technologies were of interest:

- Minimizing blood loss and optimizing fluid resuscitation.
- Treatments to prevent secondary damage after hemorrhage or major injuries.
- Treatments for battle and nonbattle injuries.

The panel was also asked to expand the traditional far-forward focus of this technology area to include consideration of the technology investment implications (medical and nonmedical) of systems derived from the CSS/Evacuation/Hospitalization and Battle Injury functional panels.

MEDICAL CHEMICAL/BIOLOGICAL (TECHNOLOGY) PANEL

This panel examined joint service CW and BW requirements technologies designed to preserve combat effectiveness by timely provision of medical countermeasures.

The Medical Chemical Defense Research Program countermeasures include prophylaxis (topical skin protectant; biological/chemical agent scavengers), pretreatments (pyridostigmine bromide), therapeutics (advanced anticonvulsant ophthalmic ointment for vesicants) and diagnostics.

The Medical Biological Defense program countermeasures include specialized medical materiel or procedures designed to enhance protection against BW agents. Its priorities are as follows:

- To provide prophylaxis or pretreatment to prevent BW casual-
- To rapidly identify and provide diagnoses for expected BW expo-
- To treat confirmed BW exposures and provide supportive care regimens.

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